S. HRG. 101-268

TO ASSESS THE IMPACT OF PROPOSED FDA USER FEES ON SMALL BUSINESS

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS
UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

TO ASSESS THE IMPACT OF PROPOSED FDA USER FEES ON SMALL BUSINESS

JUNE 13, 1989

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TO ASSESS THE IMPACT OF PROPOSED FDA USER FEES ON SMALL BUSINESS

TUESDAY, JUNE 13, 1989

U.S. SENATE,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to notice, at 2:30 p.m. in room SR-428A, Russell Senate Office Building, Hon. Dale Bumpers (Chairman of the Committee) presiding.

STATEMENT OF HON. DALE BUMPERS, A U.S. SENATOR FROM THE STATE OF ARKANSAS

The CHAIRMAN. The Committee will come to order. The purpose of today's hearing on the issue of proposed FDA user fees is to examine a number of concerns that have been brought to my attention by companies regulated by FDA.

The Administration has proposed to collect $100 million through product review fees. FDA's annual appropriation would be reduced by that amount. It has been suggested that user fees like these are nothing more than a tax on innovation. Some have compared user fees to an excise tax in spite of the fact that we have all read the President's lips.

A real user fee is one charged by the Federal Government for a particular service or product. I am not opposed to such fees in all circumstances. The user chooses to pay a true user fee. Under the Administration's proposal, the device and pharmaceutical companies will not have a choice. Review of new or modified products will be mandatory under the Food, Drug and Cosmetic Act.

OMB Circular A-25 has made it clear since 1959 that the direct beneficiary of a service or product pays, but who is the real beneficiary of FDA's services? If a device company pays a fee up front and its product is never approved for marketing, certainly they receive no benefits.

I believe most of us will agree that the consumer is the ultimate beneficiary, since it is he or she who is assured safe and effective products.

The cost of regulatory compliance to American companies is already staggering. I am interested in learning from our witnesses just what is required of them to get products approved and examples of the cost of the development and testing of a product.

Other concerns that have been brought to my attention include the question of whether the FDA can actually collect $100 million that the Administration has proposed to be cut from their budget

and whether a truly fair and equitable User Fee Program can actually be implemented.

Some have suggested the potential for conflict of interest. If smaller companies were charged a lower fee or even exempted from user fees, would the agency not be tempted even subconsciously to consider the more lucrative reviews first?

Perhaps worst of all, the companies would be discouraged from developing vital new drugs and devices intended for limited markets. With the crisis of AIDS facing our country and the remarkable advances being made in attacking this costly disease, this is hardly the time to discourage innovation.

This Committee has no jurisdiction over legislation that would have to be enacted before the user fee proposal could be implemented. The Committee on Labor and Human Resources has to struggle with the public policy questions, and there are a lot of them to be answered. I am pleased to provide a forum in which we can examine the effects on the regulated businesses which have been the scenes of many advances in research.

The Small Business Administration's Office of Advocacy was unable to provide a witness for today's hearings but has long insisted that FDA user fees would violate the letter and the spirit of our laws and regulations. I will submit for the record comments prepared by the Office of Advocacy in 1985 in response to a regulation proposed by FDA to levy user fees on drug approvals.

[Material follows:] —

U.S. SMALL BUSINESS ADMINISTRATION
WASHINGTON, D.C. 20416

OFFICE OF CHIEF COUNSEL FOR ADVOCACY

November 4, 1985

Dr. Frank E. Young
Commissioner
Food and Drug Administration
Attention: Dockets Management Branch
(HFA - 305)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

I am writing in reference to the Food and Drug Administration's (FDA) proposed user charge regulation. Notice of the proposed regulation was published in the Federal Register on August 6, 1985 (50 Fed. Reg. 31726). The proposed rule would require persons seeking FDA review of new, abbreviated, and supplemental drug and antibiotic drug applications to pay the FDA a fee to cover the costs of the agency's review processes.[1]

The Office of the Chief Counsel for Advocacy of U. S. Small Business Administration was established by Congress under P. L. 94-304 (15 U.S.C. 634 et. seq.) to advocate the views of small business before Federal agencies. The Office of Advocacy is charged by Congress in the Regulatory Flexibility Act of 1980, P.L. 96-354 (5 U.S.C. 601 et. seq.) to monitor agency compliance with that statute. It is pursuant to this authority that we are commenting on behalf of the many small businesses to be affected by the proposed rule.

Specifically, I question the legal authority of the FDA to impose user charges for the premarket approval of new drugs. In addition, to the extent that the FDA would have such authority, I believe that the Regulatory Flexibility Act of 1980 compels the FDA to adopt less burdensome user charges for small business; in particular, the agency should exempt small businesses from the regulation and/or adopt a sliding scale of user charges based on the revenues of the applicant.

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[1]The FDA proposes a charge of $126,000 for review of full new drug and antibiotic drug applications. The proposed charge for abbreviated applications is $9,900, and supplemental applications, $16,400.

A. The FDA Lacks Authority Under the IOAA to Impose User Charges for the Premarket Approval of New Drugs

Title V of the Independent Offices Appropriations Act of 1952 (31 U.S.C. 483a) (IOAA) authorizes Federal agencies to recover the agency's costs by charging the persons receiving the services. Bureau of the Budget (now, the Office of Management and Budget) Circular A-25 sets forth the guidelines for agencies' implementation of user charges. The Circular states that user charges are appropriate where the Federal Government "provides special benefits to an identifiable recipient above and beyond those which accrue to the public at large." The Circular further provides "no charge should be made for services when the identification of the ultimate beneficiary is obscure and the service can be primarily considered as benefiting broadly the general public." The Supreme Court has upheld this construction of the statute in Federal Power Commission v. New England Power Co., 415 U.S. 345 (1974).

The FDA's premarket approval activities for new drugs exists solely for the benefit of the consuming public rather than for applicants who wish to market new drugs. The Federal Food, Drug and Cosmetic Act of 1938 (21 U.S.C. 301 et seq.) was, in part, enacted to ensure the safety and effectiveness of drugs marketed to the public. Consumers of drugs are clearly the intended and ultimate beneficiaries of the FDA's review processes. While approved NDAs and ANDAs do provide a benefit to applicants by permitting them to lawfully market drugs, the agency's function provides no special benefit to the applicant that does not flow to the public at large. Approved NDAs and ANDAs do not afford the applicant market protection, as does a patent; the FDA's approval merely certifies that the applicant has fulfilled the demands of law. In the case of NDAs and ANDAs that are reviewed by FDA but do not receive approval, there is no benefit to the applicant, only to the public which is protected from purchasing a potentially unsafe or ineffective drug.

The Bureau of the Budget apparently adopted the same reasoning in Circular A-25. The Circular provides a single example of when user charges would be inappropriate because the agency's services primarily benefit the public broadly: the licensing of biological products. There is no rational distinction between the licensing of biological products and the approval of new drugs and antibiotics; in fact, an NDA or ANDA would be required to market a vaccine which is a biological product.

B. Requirements of the Regulatory Flexibility Act

Assuming that the FDA has authority under the IOAA to impose user charges, the proposed user charges disproportionately burden small businesses and violate the requirements of the Regulatory Flexibility Act (RFA).

As you know, the RFA requires agencies to prepare initial and final regulatory flexibility analyses when a rule is anticipated to exert a "significant economic impact upon a substantial number of small entities" (5 U.S.C. 605(b)). The initial regulatory flexibility analysis (IRFA) is to include reasonable regulatory alternatives which minimize the potential economic burdens of the proposed rule on small entities (5 U.S.C. 603). The purpose of the IRFA is to insure that the agency has considered ways to reduce adverse impacts on small businesses while achieving statutory objectives.

If the head of the agency believes that there will not be a "significant economic impact on a substantial number of small entities," the agency is required to publish a certification of no impact in the Federal Register along with a "succinct statement explaining the reason for such certification" (5 U.S.C. §605(b)).

C. The FDA Incorrectly Certified the Rule and Should Prepare an Initial Regulatory Flexibility Analysis

The FDA certified that the user charge rule does not have the requisite significant impact to trigger the requirement to prepare a regulatory flexibility analysis. The agency bases its conclusion upon the belief that "the additional costs of user charges will have an imperceptible impact upon drug research incentives because the costs of drug research are so large relative to the proposed user charges" (50 Fed. Reg. 31731). It is argued in the proposal that small businesses will not be significantly affected by user charges because small firms often file abbreviated new drug application which cost only $9,900 under the proposed regulation, as compared to $126,000 for a full new drug application.

The FDA failed to recognize the rule's potential impact on small business. The agency's decision to certify that the rule has no significant impact is erroneous. Statistics from the Office of Advocacy's Small Business Data Base clearly indicate that the rule will exert a significant economic impact on a substantial number of small entities.

1. The proposed rule will potentially affect a substantial number of small entities

The drug manufacturing industry is not solely the province of big business but, in fact, is heavily populated by small firms. In 1982, there were approximately 830 firms engaged in the manufacture or processing of pharmaceutical preparations.[2] Approximately 67? of these firms employed less than 50 workers. Average sales for these firms were approximately $673,000; this is compared to average sales of approximately $389 million for firms with more than 100 workers.

The number of small firms potentially affected by the user charge rule also includes small businesses that do not manufacture but develop and promote new drugs. It is very difficult to estimate this number. In addition, it is difficult to document the increasing drug development activities of small businesses in related industries, such as genetic engineering and medical device development.

While only some of these small businesses actually file NDAs and ANDAs in a given year, the proposed user charges will likely prevent many small businesses from filing applications for the first time and entering the new drug market.

2. The economic impact of the proposed user charges on small business will be significant

The FDA incorrectly concludes that the economic effect on small pharmaceutical firms will not be "significant." Many small companies file full new drug applications (NDAs) and, under the proposed rule, will be forced to pay the FDA $126,000. While this amount may be a "drop in the bucket" for large pharmaceutical firms with multimillion dollar research and development budgets, this amount may be prohibitive for the many small firms that earn their livelihood based on the marketing of as few as one or two or three drugs that have relatively low developmental costs. As previously discussed, these small businesses do not have high annual sales revenues relative to the revenues of larger firms.

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[2]The 4-digit Standard Industrial Classification (SIC) code number for this industry is 2834, "pharmaceutical preparations." This classification includes firms primarily engaged in manufacturing, fabricating or processing drugs in pharmaceutical preparations for human or veterinary use.

The proposed charge of $9,900 for an abbreviated new drug application (ANDA) is clearly less burdensome for small firms than the costs for a full NDA; however, as the FDA itself recognized, the charge may reduce the number of ANDAs filed by small firms.

I believe that the proposed user charges will have a serious adverse impact on small business. The proposed charges will not only restrict the activities of small businesses currently developing new drugs, but will present a formidable barrier to those small firms wishing to enter the new drug market. The overall effect of the proposed charges will be to eliminate small businesses from the market, leaving the industry concentrated in the hands of a very small number of very large firms.

The loss to the public from restricting small business competition and innovation will also be significant. Small businesses have been responsible for developing and bringing many new drugs to the American market that otherwise may not have been available to consumers. Some of the drugs for which small firms file NDAs are pharmaceuticals that have been successfully marketed in Europe and require FDA approval for marketing in the United States. Small businesses have carved out a "niche" for themselves in the drug marketplace; they are willing to develop and promote new drugs that have relatively limited sales potentials. For large drug companies with substantial research and development expenditures, it is not economically efficient to develop new drugs that have relatively low sales potentials.

For these reasons, I believe that the proposed user charges ("Alternative 1") will have a "significant economic impact on a substantial number of small entities." Assuming the FDA's legal authority to impose user charges, the FDA, therefore, would be required by the RFA to prepare an initial regulatory flexibility analysis (IRFA) that examines less onerous alternatives to the proposed rule.

3. None of the alternatives presented by FDA will minimize the impact of user charger on small business

In the notice of proposed rulemaking, the FDA lists two alternative user charge schedules which would more closely tie the charges to the complexity and cost to the agency of reviewing the applications. Under each of these alternatives, the user charges would be increased for some applicants and decreased for others, depending on the nature of the drug to be reviewed. Because small businesses will file both NDAs and

ANDAs for drugs of various categories, neither of the alternatives will reduce the overall burden on small business. The alternatives would merely shift costs among small businesses seeking approval for different drugs.

One approach that many agencies have taken in developing regulations to fulfill the demands of the RFA is to create an exemption for small business based on revenue. For example, in this rulemaking, firms with annual revenue of less than $5 million would be exempt from user charges. An additional, related alternative would be a sliding scale of charges that increases with firm revenue. The RFA requires agencies to discuss these alternatives in the IRFA of the proposed rule (5 U.S.C. 603 (c)).[3]

D. Conclusion

I question the FDA's authority under the IOAA to adopt user charges for the premarket approval of drugs. I believe that if the agency lacks authority to charge new drug applicants for the agency's services, the FDA should not pursue extending user fees for the review of other products, such as food and color additives, medical devices, and animal drugs.

The imposition of user charges for the premarket approval of drugs will have a serious detrimental economic impact on the many small businesses in the drug industry. To the extent that the FDA has legal authority to impose user charges, there may

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[3]Some have suggested a tiering of user charges based upon anything other than the agency's differential costs may be inappropriate under the IOAA. See Electronic Industries Association, etc. v. Federal Communications Commission (554 F.2d 1109) (D.C. Cir. 1976), and Capital Cities Communications v. Federal Communications Commission (554 F.2d 1135) (D.C. Cir. 1976). I believe that the RFA of 1980, however, would supercede this earlier construction of the IOAA and authorize a tiering of charges or an exemption for small business. The FDA's exemption for orphan drugs is similarly based on limited sales potential.

be reasonable alternatives to the proposed fees that will raise significant revenue without exacting a disproportionately high toll upon small business. Assuming the FDA's authority under the IOAA, I urge the FDA to prepare an IRFA to determine whether such workable regulatory alternatives exist. I would be pleased to provide you with any needed assistance in implementing the RFA.

Yours very truly,

Chris Caldwell for

Frank S. Swain
Chief Counsel for Advocacy

The CHAIRMAN. According to the FDA, the reviews for which the fees would be levied and the amounts are as follows:

New drug application, $300,000;
New animal drug application, $100,000;
Premarket approval application, $90,000;
Device premarket notification, $1,000;
Generic applications for human and animal drugs, $20,000;
Biologics license application review, $45,000; and
Food and color additive petitions, $125,000.

While some of these fees may not seem large in relation to the amount of effort which FDA devotes to the regulatory process, I am convinced that many small and emerging biomedical companies which are thinly capitalized in their early years would be unable to shoulder such a burden. Their only alternative would be abandoning the field or a merger into one of the pharmaceutical giants.

I doubt that I would oppose, for example, a fee on food and color additive petitions. My primary concern here is the penalizing of small companies to the point that they might find these fees to be disincentive; and second, whether or not as a public policy, where the American public and the consumer is the ultimate beneficiary, it is wise to levy a fee.

It is true that companies who succeed in this research and are finally approved take in more the first hour from the sale of a drug than these fees would amount to, and I recognize that; but it is the consumer who is the ultimate beneficiary.

Let me go back and restate one more time, this is the Small Business Committee. I am an advocate of small business, and I am not unalterably opposed to user fees where they are appropriate. I am opposed to them in all instances where they represent discrimination against small business and a disincentive for advances in development of new or improved drugs and devices.

[The prepared statements of Senators Dixon, Wallop, and Grassley follow:]

JUNE 13, 1989

STATEMENT BY ALAN J. DIXON

SMALL BUSINESS COMMITTEE

HEARING ON FDA USER FEES

MR. CHAIRMAN, WE ARE HERE TODAY TO EXAMINE THE IMPACT OF PROPOSED FOOD AND DRUG ADMINISTRATION USER FEES ON SMALL BUSINESSES ACROSS THE NATION. I COMMEND THE CHAIRMAN FOR HOLDING THIS HEARING. THIS SESSION WILL PROVIDE THE OPPORTUNITY FOR THE CONCERNS OF SMALL BUSINESSES TO BE HEARD. ALTHOUGH SMALL BUSINESSES COMPRISE A FRACTION OF THE ENTIRE INDUSTRY, SMALL BUSINESSES PROVIDE INNOVATIVE SOLUTIONS TO CHALLENGES IN THE DRUG AND DEVICE INDUSTRY, AS THEY DO IN MANY OTHER INDUSTRIES.

THE USER FEES PROPOSED BY THE ADMINISTRATION ARE FOR THE REVIEW OF NEW DRUGS AND DEVICES BY THE FOOD AND DRUG ADMINISTRATION. THE FOOD AND DRUG ADMINISTRATION MUST SIGN OFF ON ANY NEW DRUG OR DEVICE BEFORE THE PRODUCT IS MARKETED TO INSURE THE PRODUCT'S SAFETY AND EFFECTIVENESS, NECESSARILY A VERY IMPORTANT ROLE. HOWEVER, SINCE MOST BUSINESSES MUST OPERATE IN THE RED WHILE THEY COMPLETE THE DEVELOPMENT OF NEW PRODUCTS, THE IMPOSITION OF USER FEES TO PERFORM REVIEWS MAY

STIFLE, IF NOT STOP, THE RESEARCH ACTIVITIES OF SMALL FIRMS. THIS RESULT WOULD NOT BE DESIRABLE.

THE OPPORTUNITY TO HEAR FROM THE ADMINISTRATION AND SMALL BUSINESSES WILL BE VALUABLE IN OUR DELIBERATIONS ON THE PROPOSED FEES. I LOOK FORWARD TO HEARING FROM THE DISTINGUISHED WITNESSES. THANK YOU, MR. CHAIRMAN.

STATEMENT BY SENATOR MALCOLM WALLOP
REGARDING PROPOSED FOOD AND DRUG ADMINISTRATION USER FEES
FOR REVIEW OF APPLICATIONS FOR NEW DRUGS AND MEDICAL DEVICES
BEFORE THE SMALL BUSINESS COMMITTEE
TUESDAY, JUNE 13, 1989

Mr. Chairman, I appreciate your efforts to bring this hearing to order today to discuss the ramifications of the Administration's proposal to implement user fees for the review of new medical device and new, abbreviated and supplemental drug applications. I will tell you quite frankly that I have very strong reservations about this proposal. My concerns have also been reinforced by comments I received from the small medical device companies in Wyoming which I notified about possible user fees. I'd like to enter the letters I received from those companies into the hearing record at this point and summarize their concerns -- and mine -- about the effect of user fees on their ability to continue effective research and development in new drugs and medical devices.

I would note that these user fees have been under consideration about since 1985, but due to the opposition of several influential members of Congress, the Small Business Administration and a large number of pharmaceutical companies, they were never implemented. In fact, Congress never acted on legislation introduced in 1986 and 1987.

Yet, due to a budget shortfall of $100 million in appropriations, which includes a $61 million cutback in appropriations for basic operations from the current fiscal year, Congressman Madigan of Illinois has agreed to offer the Administration's user fee package this year. This bill, H.R. 2482, known as the New Drug and Device Application Fee Amendments of 1989, would authorize the Secretary of Health and Human Services to issue regulations on user fees and allow the funds collected to be credited to FDA's account for salaries and expenses.

Based on the information submitted by the FDA on its FY 90 budget, there is no connection between the payment of user fees by a particular regulated industry and the use of the receipts to improve FDA operations affecting that industry's products. I might also point out that for the last several years, the Agriculture Appropriations bills, which include funding for FDA, have included provisions prohibiting the use of any funds by FDA to implement a user fee program. The FDA user fee would be a new tax on innovation, not a user fee. Also, it would not be voluntary because FDA premarket review of health and food products is mandated by law.

With that in mind, I would be remiss if I didn't question the legal authority of the FDA to impose user fees for the premarket approval of new drugs. According to OMB circular A-25, the "licensing of new biological products" is a service for which user fees are not appropriate because "the service can be primarily considered as benefitting broadly the general public."

Interestingly enough, one of my staff members has a digestive disease for which there is currently no FDA-approved drug for treatment. Recently, however, she learned that an experimental drug, known as cisapride, was available at four medical centers in the United States, one of which is Johns Hopkins Hospital in Baltimore, Maryland. Cisapride was developed by a pharmaceutical company in Brussels, Belgium, Janssen Pharmaceuticals, and is still in the testing stages.

In order to qualify for the protocol for this drug, my staff member went through a series of tests and agreed to go through another 12 week blind test period. She is also free to drop out of this protocol at any time. Under the blind test, she has been given a drug, but neither the doctors monitoring the testing nor my assistant know whether or not it is a placebo or the real drug. My staff member also must go through two additional three-day test periods to monitor any improvements in her symptoms. After the 12-week test period, she will be given the real drug for up to two years or until it has been approved by the FDA. In addition to being given free drugs, all of the tests and other hospital-related expenses incurred by my staff member are paid for by Janssen Pharmaceuticals.

Mr. Chairman, my point in all this is that if user fees were implemented to the extent that the Administration has proposed -- up to $300,000 for a new drug application -- pharmaceutical companies like Janssen which research and develop drugs for rare diseases could be deterred from continuing those vital efforts. In my view, user fees would impede economic growth and undermine the competitiveness of American companies in international markets. The pharmaceutical industry's investment in research and development has been doubling every five years since 1970. The FDA should be equipped with the money to carry out its work to review new drugs and health and food products, but without resorting to user fees. Prompt approval by the FDA of new drug applications is essential to the health of the American people and to the continued prosperity of small pharmaceutical and medical device companies which greatly contribute to that endeavor. I hope my colleagues will join me in opposing any attempts to enact H.R. 2482 or similar proposals to implement user fees for new drugs and medical devices.

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MEDTECH LABORATORIES, INC.
P.O. Box 1108 Jackson, Wyoming 83001 1-(800)443-4908

DATE: June 12, 1989

TO: Sen. Malcom Wallop

FROM: Carl J. Schmidlapp
Vice President-Regulatory Affairs
Medtech Laboratories, Inc.
Jackson, WY 83001

RE: H.R. 2482 - FDA User Fees

I am strongly opposed to the proposed fees for the following reasons.

With the growing concern over both the quality and costs of health care, these fees will only add to the financial burden of companies developing new products. These new charges will be invariably added to the cost for the consumer.

It will set a bad precedent for the additional fees being levied for just about anything the government feels necessary in order to make up shortfalls when the real problem is the control of the budget in the first place. Talk about taxation without representation.

It will place a tremendous burden on smaller companies in the generic business. Again this will result in higher costs passed on the public. It will literally drive generic suppliers from the market place when at a time generic suppliers have finally gained the recognition that their formulations are just as good as the branded names. I see a real impact on the older person who may have little or no health insurance.

Thank you for giving us the chance to speak out.

Carl J. Schmidlapp

CompuMed, Inc. TEL No.307-[illegible]-2550 Jun.12.89 11:03 P.01

CompuMed, Inc.

June 12, 1989

The Honorable Malcolm Wallop
United States Senator
Dirksen Building
Washington, D.C. 20510

Dear Senator Wallop:

Thank you for the opportunity to respond to H.R. 2482.

CompuMed urges the non-passage of this bill for the following reasons:

1. The constitutional responsibility of "general welfare" should be borne generally, not specifically. This bill is an effort to shift healthcare costs from an appropriation base to a user base. It runs contrary to the intent of the Constitution and the Federal Food, Drug, and Cosmetic Act. What benefits one benefits all.

2. Healthcare innovations, particularly in the area of medical devices, often come from small businesses or inventors. Unlike large medical and pharmaceutical companies, small businesses may not have the financial wherewithal and "staying" power to service the review fees - a cost of both money and time.

3. The review fees may effectively prevent many worthwhile medical products from reaching the market because of the added review costs. Many medical products save time, money and health for the ultimate patient. Such savings would be non-existent if the product never reached the patients.

4. As the nation grows grayer and has more healthcare concerns, there will be an increasing effort to shift healthcare costs. The user fee as proposed in H.R. 2482, if enacted, would shift the review costs to the manufacturers and product developers. It would not be long, though, before these "costs" would be shifted to the ultimate "shiftee" - the consumer.

We appreciate all you do, Senator Wallop, for us here in Wyoming. We are well represented.

Give our best to French and your excellent staff.

Sincerely,

Steven A. Christiansen

Steven A. Christiansen
VP Marketing & Finance

STATEMENT OF SENATOR CHARLES E. GRASSLEY AT A HEARING OF THE SENATE SMALL BUSINESS COMMITTEE ON THE SUBJECT OF USER FEES FOR APPROVAL BY THE FOOD AND DRUG ADMINISTRATION OF NEW DRUG AND DEVICE APPLICATIONS.

THANK YOU, MR. CHAIRMAN. I HAVE A BRIEF STATEMENT.

THE USER FEE PROPOSAL WHICH IS THE SUBJECT OF THIS HEARING IS A CURIOUS THING. IT DOESN'T SEEM TO HOLD WATER FROM WHATEVER ANGLE YOU LOOK AT IT. AND, FURTHERMORE, IT SEEMS UNLIKELY THAT THE CONGRESS WILL IMPLEMENT ANYTHING LIKE IT THIS YEAR. NEVERTHELESS, IT GENERATES A LOT OF CONCERN AMONG THE PEOPLE WHO WOULD HAVE TO PAY THE USER FEE.

FOR THAT REASON, MR. CHAIRMAN, I THINK THAT THIS HEARING DOES A SERVICE BY GETTING SOME SYSTEMATIC DISCUSSION OF THIS MATTER INTO THE PUBLIC RECORD.

AS FAR AS I CAN TELL, MR. CHAIRMAN, IT IS VERY UNLIKELY THAT THE CONGRESS WILL IMPLEMENT A USER FEE FOR THE FOOD AND DRUG ADMINISTRATION.

NOW, IT IS THE CASE, OF COURSE, THAT THERE IS A KIND OF "PHANTOM" $100 MILLION IN FUNCTION 550 OF THE BUDGET. IT IS $100 MILLION THAT IS NOT DISCUSSED IN THE RESOLUTION, AND IS NOT RECONCILED TO ANY COMMITTEE, BUT NEVERTHELESS SHOWS UP IN THE BOTTOM LINE FOR THE FUNCTION.

IT SEEMS TO ME THAT THIS IS MORE A PROBLEM FOR THE ULTIMATE LEVEL OF THE DEFICIT FOR FISCAL YEAR 1990 THAN IT IS FOR THE PEOPLE ON WHOM A USER FEE WOULD BE LEVIED. THE CHAIRMAN AND THE RANKING MINORITY MEMBER OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES ARE BOTH STRONGLY OPPOSED TO AN FDA USER FEE. AS I UNDERSTAND IT, A USER FEE SHOULD HAVE AUTHORIZING LEGISLATION. GIVEN THE OPPOSITION TO IT FROM THE LEADERSHIP OF THE LABOR COMMITTEE, AUTHORIZING LEGISLATION SEEMS UNLIKELY.

THE SUBCOMMITTEE ON AGRICULTURE OF THE SENATE APPROPRIATIONS COMMITTEE, OF WHICH I AM A MEMBER, HAS, FOR SEVERAL YEARS NOW, EXPLICITLY OPPOSED USER FEES FOR THE FOOD AND DRUG ADMINISTRATION. AT THE MOMENT, IT DOESN'T SEEM LIKELY THAT THE SUBCOMMITTEE WILL DEVIATE FROM THAT POLICY.

THANK YOU, MR. CHAIRMAN. I AM LOOKING FORWARD TO THE TESTIMONY OF OUR WITNESSES.

The CHAIRMAN. Our first witness today is Mr. James Benson, Acting Deputy Commissioner, Food and Drug Administration.

Mr. Benson, we are very pleased to have you.

I will ask all witnesses if possible to summarize your statements. Your full text will be admitted to the record.

Welcome again, Mr. Benson. Please proceed.

STATEMENT OF JAMES S. BENSON, ACTING DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD, ACCOMPANIED BY FRANK CLAUNTS, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT; TOM SCARLETT, GENERAL COUNSEL; AND JOE LEVITT, DIRECTOR, OFFICE OF EXECUTIVE OPERATIONS

Mr. BENSON. Thank you, Senator. I appreciate the opportunity to be here. Let me introduce quickly the folks that are here with me: Joe Levitt, who directs our Office of Executive Operations; Tom Scarlett, who is the General Counsel for the agency; and Frank Claunts, who heads up our Financial Management Division.

Before addressing the issue of user fees, I would like to take this opportunity to describe briefly some of the Agency's ongoing programs to support and encourage technological innovation by the small business community.

I think we recognize that small business is vital to the growth and future of our country and national economy. Often the innovation, dynamism, and entrepreneurial attitude of the American free enterprise system is concentrated in small businesses. They account for approximately 40 percent of our GNP, contribute two out of three new jobs, and produce twice as many innovations per employee as larger firms. They spend proportionately twice as much on research as large firms. The small business person in the Nation symbolizes the independence, freedom, and perseverance that have long been identified with the American way of doing things. We believe it is imperative that Government regulatory programs be designed such that they do not dampen competition which is the foundation of our free enterprise system.

The costs of regulatory compliance may sometimes place a disproportionately large burden on small businesses. The majority of the firms regulated by FDA—foods, drugs, medical devices, cosmetics, and veterinary products—are classified as small businesses. The Agency makes every effort to minimize regulatory burdens consistent with the law in order to encourage technological innovation, which in turn, can lead to improvements in the public health.

As part of the Agency's strategy to foster new technology, FDA has assisted small business in complying with admittedly burdensome, albeit necessary, regulation.

Through our Small Business Assistance Program we encourage small business representation on FDA's advisory panels, seek the views and opinions of the small business community about regulatory issues and proposals before any final action is taken, provide small business with access to all levels of the Agency, and generally provide assistance whenever possible to firms with limited resources in their interactions with the Agency.

Each FDA region has a local contact or Small Business Representative (SBR). These SBRs devote much of their time to minimizing the regulatory burdens for small business by providing these small firms with current information and technical assistance, by clarifying and interpreting FDA rules and regulations, and explaining registration and reporting requirements. The SBRs conduct workshops and seminars designed to help small business understand and comply with appropriate laws and regulations. They also perform on-site visits to review and analyze problems that concern the firms.

Small businesses are particularly prevalent in the medical device industry. This industry is a young, vibrant one, characterized by rapid growth and advanced technological innovation. Recent data indicates that over 90 percent of the medical device firms have fewer than 500 employees.

FDA's Center for Devices and Radiological Health (CDRH), has worked vigorously to establish a climate that generally benefits the marketing of devices that might otherwise languish. In order to ensure that this important new technology reaches the American public, CDRH has established a Division of Small Manufacturers Assistance that provides technical and other nonfinancial assistance to device manufacturers. The primary purpose of the division is to offer expert regulatory assistance to those who wish to market a medical device.

Another important area where the Agency has served as a catalyst for technological innovation is in orphan products development. Many of the companies developing orphan products are smaller firms.

Congress passed the Orphan Drug Act in 1983 that contained a number of incentives to make orphan drugs more readily available to Americans who suffer from these rare diseases or disorders. These incentives include marketing exclusivity, tax credits for research costs, and a grant and contracts program to help to defray the cost of clinical tests associated with the development of orphan drugs. In the period since enactment of the Orphan Drug Act, the FDA has conducted hundreds of meetings to provide information to prospective sponsors, assist them in meeting various provisions of the act, advise on clinical studies to be conducted, and provide guidance on the process for applying for marketing approval of an orphan drug. To date, 276 drugs have been designated as orphans.

The Commissioner and I are continually working to make the agency more user-friendly. Much emphasis is being placed on communicating our requirements so as to make it easier for applicants. This is especially critical for small businesses.

Let me now turn to the user fee issue. The Administration proposal on user fees would provide FDA with the authority to charge up to the full cost of reviewing various applications for marketing approval for food additives, human and animal drugs, antibiotics, medical devices, and biological products. The revenue generated from these fees would be retained by FDA to support the specific activity. For example, the fees collected from firms that apply to market new or generic animal drugs would be applied to the cost of that part of FDA's operations in the Center for Veterinary Medicine. The resources generated by user fees would help to ensure the

necessary resources to continue to conduct high quality and timely reviews of new product applications. The Agency believes that user fee authority is fair and appropriate because it shifts the substantial costs of review of these products from the taxpayers to the producers and manufacturers who profit from the products approved by FDA.

The proposal, however, also recognizes that there may be a need for special exemptions in certain circumstances. For example, the proposal includes authority for the Secretary to waive fees in exceptional circumstances in the public interest. We would expect that this could include some applications for orphan products and some exemptions for small business. This is an area where we would want to consider in detail the concerns and recommendations of the Committee.

We estimate that about $100 million could be collected annually under this proposal. This number is based on our estimate of the costs of the programs for which fees will be charged. The exact fees, of course, would have to be set after Congress passed the legislation and we performed an in-depth audit of the costs involved and updated the estimate of the numbers of applications we would expect to receive. The timing of the legislation and budget cycle are very important to ensure that the needed revenue stream for proper agency function is maintained.

The Agency has considered the effects of user charges upon firms submitting applications, particularly with regard to any reduced incentive to conduct research or develop products. In the case of drug firms, the Agency concluded that user charges will have a very small impact upon drug research incentives because the costs of drug research are so large relative to the proposed user charges. In most cases, the fee paid to FDA would be a small fraction of the projected income that the manufacturer expects to receive from the product in just the first year.

Moreover, the user fee provision could be written in such a way to raise additional resources which in turn could be used to enhance and accelerate the application approval process. With a shorter application period, industry could experience increased profits.

In this case, enhanced industry profits could result in increased research and development and assist small businesses. Hence, the impact of user fees upon product development costs, industry profits, and research and development would depend upon how user fees are set and how they impact upon the application approval process at FDA.

FDA also recognizes its responsibility under the Regulatory Flexibility Act in achieving the statutory goals of this proposal as effectively and efficiently as possible without imposing unnecessary burdens on small businesses. When the Agency develops regulations to establish the fee structure and implements the enacted proposal, it will carefully review the legislative record for guidance on the fee structure considerations and will strive to implement the legislative provision for waiver and reduction of fees in a manner that is consistent with legislative intent.

The regulatory programs administered by FDA are important to the safety and health of the Nation. The Agency makes every

effort to achieve public health goals in ways that minimize the burden on small business. This philosophy is at the heart of numerous FDA small business activities. It will continue to provide the basis for any future decisions regarding the imposition of user fees.

Thank you, Mr. Chairman. If you have any questions, I will be pleased to try to answer them.

[The prepared statement of Mr. Benson follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

JAMES S. BENSON

ACTING DEPUTY COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

June 13, 1989

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

I appreciate the opportunity to testify today on the Administration's proposal for user fees as it relates to FDA. Before addressing the issue of user fees, I would like to take the opportunity to describe briefly the Agency's ongoing programs to support and encourage technological innovation by the small business community.

Background

Small business is vital to the growth and future of our country and national economy. Often the innovation, dynamism, and the entrepreneurial attitude of the American free enterprise system is concentrated in small businesses. They account for approximately forty percent of our GNP, contribute two out of three new jobs, and produce twice as many innovations per employee as larger firms. They spend proportionately twice as much on research as large firms. The small business person in the Nation symbolizes the independence, freedom, and perseverance that have long been identified with the American way of doing things.

It is imperative that government regulatory programs be designed such that they do not dampen competition which is the foundation of our free

enterprise system. The costs of regulatory compliance may sometimes place a disproportionately large burden on small businesses. The majority of the firms regulated by FDA--foods, drugs, medical devices, cosmetics, and veterinary products--are classified as small business. The Agency makes every effort to minimize regulatory burdens in order to encourage technological innovation, which in turn, can lead to improvements in the public health.

FDA Assistance for Small Business

As part of the Agency's strategy to foster new technology, FDA has assisted small businesses in complying with admittedly burdensome, albeit necessary, regulation. Through our Small Business Assistance (SBA) program we encourage small business representation on FDA's advisory panels, seek the views and opinions of the small business community about regulatory issues and proposals before any final action is taken, provide small business with access to all levels of the Agency, and generally provide assistance whenever possible to firms with limited resources in their interactions with the Agency. Each FDA Region has a local contact or Small Business Representative (SBR). SBRs devote much of their time to minimizing the regulatory burdens for

small business by providing these small firms with current information and technical assistance, by clarifying and interpreting FDA rules and regulations, and explaining registration and reporting requirements. SBRs conduct workshops and seminars designed to help small business understand and comply with appropriate laws and regulations. They also perform on-site visits to review and analyze problems that concern the firms.

Small businesses are particularly prevalent in the medical device industry. This industry is a young, vibrant one, characterized by rapid growth and advanced technological innovation. Recent data indicate that over ninety percent of medical device firms have less than five hundred employees.

FDA's Center for Devices and Radiological Health (CDRH) has worked vigorously to establish a climate that generally benefits the marketing of devices that might otherwise languish. In order to ensure that this important new technology reaches the American public, CDRH has established a Division of Small Manufacturers Assistance that provides technical and other nonfinancial assistance to device manufacturers. The primary purpose of this Division is to offer expert regulatory assistance to those who wish to market a medical device. Over three-fourths of device manufacturers have heard of this program, and of those, almost half have used these services.

Another important area where the Agency has served as a catalyst for technological innovation is in orphan products development. Many of the companies developing orphan products are smaller firms. The absence of incentives for companies to invest in the development of treatments for rare diseases had long been recognized as a public health problem. In the past, the considerable costs involved in conducting appropriate laboratory, animal and human studies to establish safety and effectiveness often discouraged companies, especially small companies, from pursuing the development of orphan drugs with limited sales potential. There was widespread agreement that every reasonable effort should be made to ensure that our citizens are not denied vital medical therapies simply because an adequate return on investment might be lacking. As a result of this concern, Congress passed the Orphan Drug Act of 1983 that contained a number of incentives to make orphan drugs more readily available to Americans who suffered from these rare diseases or disorders. These incentives include marketing exclusivity, tax credits for research costs, and a grant and contracts program to help defray the cost of clinical tests associated with the development of orphan drugs.

The Agency is proud of its accomplishments in helping the small business community foster the development of products for rare diseases and conditions. Our Office of Orphan Drug Products has served as a

catalyst for the development of important new drugs, stimulating interest and funding critical studies. This Office makes special efforts to meet at early stages with interested companies (many of whom are smaller companies) to help plan the development program and to define needed studies. In the period since enactment of the Orphan Drug Act, the FDA has conducted hundreds of meetings to provide information to prospective sponsors, assist them in meeting various provisions of the Act, advise on clinical studies to be conducted, and provide guidance on the process for applying for marketing approval of an orphan drug. To date, 276 drugs have been designated as orphans, including products for a wide range of rare conditions such as Wilson's disease, Tourette's syndrome, and leprosy. There have been 37 designations for recombinant drug and biological products--products that are on the cutting edge of technology. While some concerns have been raised that certain orphan drugs may have potentially lucrative sales or multiple competing patents, the program has, on balance, been very effective.

User Fees

The Administration proposal on user fees would provide FDA with the authority to charge up to the full cost of reviewing the various applications for marketing approval for food additives, human and animal drugs, antibiotics, medical devices, and biological products. The revenue generated from these fees would be retained by FDA to

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support the specific activity. For example, the fees collected from firms that apply to market new or generic animal drugs would be applied to the cost of that part of FDA's operations in the Center for Veterinary Medicine and other parts of FDA that are necessary to review those applications. The resources generated by user fees would help to ensure the necessary resources to continue to conduct high quality and timely reviews of new product applications. The Agency believes that user fee authority is fair and appropriate because it shifts the substantial costs of review of these products from the taxpayers to the producers and manufacturers who profit from the products approved by FDA.

The proposal, however, also recognizes that there may be the need for special exemptions in certain circumstances. For example, the proposal includes authority for the Secretary to waive fees in exceptional circumstances in the public interest. We would expect that this could include some applications for orphan products and some exemptions for small businesses. Because orphan drugs, by statutory definition, are developed primarily for public health reasons and not for the benefit of the sponsor, the Agency believes it may be inappropriate to impose user charges for these products. This is an area where we would want to consider in detail the concerns and recommendations of the Committee.

Legislation is necessary to implement these fees, because of a recurring statutory prohibition in our appropriations that precludes FDA from using the general authority of the user fee act, 31 U.S.C. 9701, to implement new user fees. The proposal, however, is consistent with the tradition of that act, OMB Circular A-25, and previous court decisions in that fees collected would be limited to FDA costs in performing certain services.

We estimate that about $100 million could be collected annually under this proposal. This number is based on our estimate of the costs of the programs for which fees would be charged. The exact fees, of course, would have to be set after Congress passed the legislation and we performed an in-depth audit of the costs involved and updated the estimate of the numbers of applications we would expect to receive. The timing of the legislation and budget cycle are very important to ensure that the needed revenue stream for proper Agency function is maintained.

The Agency has considered the effects of user charges upon firms submitting applications, particularly with regard to any reduced incentive to conduct research or develop products. In the case of drug firms, the Agency concluded that user charges will have an imperceptible impact upon drug research incentives, because the costs of drug research are so large relative to the proposed user charges. In most cases, the fee paid to FDA would be a small fraction of the

projected revenue the manufacturer expects to receive from the product in just the first year. There are many other cases where industry or the public pay for government service, and we believe that the fees, compared to the tremendous scope of the industries we regulate, would not have a significant impact either on the firms or on technological innovation.

Moreover, the user fee provision could be written in such a way to raise additional resources which in turn could be used to enhance and accelerate the application approval process. With a shorter application period, industry could experience increased profits. For example, according to one recent estimate, if drug application review times are reduced from 24 to 12 months, pharmaceutical industry profits could increase by $74 million annually. For the medical device industry, a one month change in the length of device review could result in $100 million in additional industry profits. It is possible that the additional profits would exceed the level of user fees paid by a particular industry, meaning the industry will profit from accelerated product approvals. In this case, enhanced industry profits could result in increased research and development and assist small businesses. Hence, the impact of user fees upon product development

costs, industry profits, and research and development would depend upon how user fees are set and how they impact upon the application approval process at FDA.

FDA also recognizes its responsibilities under the Regulatory Flexibility Act in achieving the statutory goals of this proposal as effectively and efficiently as possible without imposing unnecessary burdens on small businesses. In designing any fee structure, FDA believes that it is essential to ensure that the share of fees collected from smaller innovators is not disproportionate to the share of Agency effort devoted to reviewing applications from that sector. Accordingly, we recognize that a fee appropriate for reviewing a voluminous and complex submission may be both inappropriate and unfair for a much simpler application of the same type. When the Agency develops regulations to establish the fee structure and implement the enacted proposal, it will carefully review the legislative record for guidance on the fee structure considerations and will strive to implement the legislative provision for waiver and reduction of fees in a manner that is consistent with legislative intent.

Conclusion

The regulatory programs administered by FDA are important to the safety and health of the nation. The Agency makes every effort to achieve

public health goals in ways that minimize the burden on small business. This philosophy is at the heart of numerous FDA small business activities. It will continue to provide the basis for any future decisions regarding the imposition of user fees.

Thank you, Mr. Chairman. If you or members of the Committee have any questions, I will be pleased to answer them.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 18 1989

The Honorable Dale Bumpers
Chairman
Committee on Small Business
United States Senate
Washington, D.C. 20510-6350

Dear Mr. Chairman:

This is in response to your letter of June 20, 1989, requesting answers to questions submitted by Senator Wallop regarding Mr. Benson's June 13 testimony on user fees before your Committee on Small Business. We hope the following responses are helpful.

1. Question: What fee scale do you envision for the imposition of user charges for the approval of new drug (sic) and medical devices?

Answer: The legislative proposal itself does not include specific fees. Our estimate of $100 million that could be collected is based on our estimate of the costs of the programs for which fees would be charged. The exact fees, of course, would have to be set after Congress passed the legislation and we reviewed the costs involved and the numbers of applications we expect to receive. Also, we would have to take into account any specific guidance specified by Congress on how fees are to be set. Based on our rough estimates of the costs of reviewing the different types of applications, and the numbers we currently receive, the fee for a New Drug Application would be about $300,000. The fee for a New Animal Drug Application would be about $100,000, and the fee for generic applications for both human and animal drugs would be in the range of $20,000. The fee for a medical device Premarket Approval Application would be about $90,000, and the fee for device premarket notifications -- known as 510(k)s -- would be about $1,000. These estimates assume a flat fee would be set for all of one particular type of application.

2. Question: If this were to be a sliding fee scale, would you implement it based on the size of the company applying for approval of a new drug or medical device or the amount of work entailed in reviewing the application?

Answer: Whether sliding fee scales are set will depend on the guidance FDA receives from Congressional consideration of the user charge proposal. There are two separate issues here -- adjusting the fee based on the work required of FDA, and adjusting fees by the size of the business submitting the application. FDA has considered the idea of separate fees within the types of product applications. For example, some types of New Drug Applications and Premarket Approval

Applications for devices are far more complex than others, especially when the product represents an entirely new chemical entity or technology. Charging more for such applications may be a consideration, however, it might be hard to establish precise guidelines for when higher fees are charged for applications within a category and when they are not.

Regarding different fees for different businesses, this is an issue where FDA would hope for guidance from Congress as it considers the proposal. Although overall the Agency believes that the user fees proposed would not have an impact on product development, there might be cases where lesser fees for small businesses might be warranted, especially for the major types of applications that require substantial effort from FDA -- New Drug Applications and device Premarket Approval Applications.

3. Question: How can you justify these fees when it so clearly runs in against the intent of OMB Circular A-25 which states that "no charge should be made for services when the identification of the ultimate beneficiary is obscure and the service can be primarily considered as benefiting broadly the general public."?

Answer: First, FDA's proposal for user fees has been transmitted to the Congress as a separate legislative proposal, and is not proposed to be implemented under current statutory authority or under the guidelines of Circular A-25. However, the Administration believes that although the public benefits from FDA's product review functions as well, the firm submitting the application is clearly the immediate economic beneficiary. Except in a few cases such as for orphan products, firms submit applications so that they can market their products to make profits, and FDA's determination that a product is safe and effective clearly benefits firms in marketing their products.

If we can be of any further assistance, please let us know.

A similar letter has been sent to Senator Boschwitz.

Sincerely yours,

Donna Tenka for

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

The CHAIRMAN. Thank you very much.

Mr. Benson, on page 6 of your testimony you state that the resources generated by user fees would help to ensure the necessary resources to continue to conduct high quality and timely reviews of new product applications.

Is that to say that if you do not get the user fees you will not be able to continue the high quality and timely reviews of the Agency?

Mr. BENSON. The user fee proposal amounts to about one-fifth of FDA's budget.

The CHAIRMAN. You anticipated my next question.

Mr. BENSON. There is no question that if we do not get that full figure, some severe changes in the Agency would have to be made and I am sure would have a definite impact on product approval, yes.

The CHAIRMAN. Mr. Benson, the Administration proposes and, as I understand it, it is well understood by FDA that if you do get the $100 million, your appropriation is going to be cut by a corresponding amount. So how does FDA come out any better off?

Mr. BENSON. I think from a budget standpoint we would be no better off if that $100 million were offset with user fees as opposed to coming through appropriations.

I think the issue is what is the fairest way to pay for the product approval process.

The CHAIRMAN. This sentence does not make much sense, then, that this is going to enable you to better perform your duties, does it?

Mr. BENSON. I am sorry. I did not find the reference.

The CHAIRMAN. Page 6, the first paragraph, second sentence. "The resources generated by user fees will help to ensure the necessary resources to continue to conduct high quality and timely reviews."

Mr. BENSON. Well, if it were a choice between not having the $100 million versus having it through user fees, then this sentence would definitely apply.

The CHAIRMAN. I might be more favorably disposed toward user fees if you were going to get the money and hire some additional people to speed up the reviews of applications, which is the complaint we get constantly from the industry.

Mr. BENSON. I think that over the past 4 years especially we have really done a great deal to streamline the approval process, but if you look back over the past 10 years or so, FDA's staffing resources have not increased. In fact, they have gone the other direction.

So I think with an increased workload that we find in many areas, it is difficult to keep up with that workload with the present level of resources.

So I guess I would agree that it would be very helpful to have additional resources to speed up the applications process. I think if that were to happen, everyone would benefit.

The CHAIRMAN. Let me ask you about FDA's actual cost. In my opening statement I listed what your tentative fee list was. Was that a fairly accurate summation?

Mr. BENSON. It is an accurate summation.

The CHAIRMAN. I realize this is not final.

Mr. BENSON. I wanted to stress that fact. In fact, if you will allow me, I would appreciate the opportunity to do that.

The CHAIRMAN. Let us take the new drug application, NDA. Your tentative proposal is $300,000 for a new drug application. Now what is FDA's actual cost of processing a new drug application?

Mr. BENSON. Before I answer that, let me say that I want to stress the indefiniteness of those numbers. They were rough estimates that we used to give an idea of what the fees might be.

The way those numbers were generated was simply to add up the costs of the various approval processes. In the case of the new drug applications it would be our estimate of the cost of that process simply divided by the number of applications that come in. So the answer is $300,000 on average.

The CHAIRMAN. So you say you are collecting your full fee, then, your full cost on that?

Mr. BENSON. Yes, that is correct.

The CHAIRMAN. I understood you to say a while ago that these fees would only cover one-fifth of your cost.

Mr. BENSON. I was referring to the full FDA budget which includes, of course, product surveillance, various enforcement actions, educational research, and so on.

The CHAIRMAN. What is FDA's total budget?

Mr. BENSON. Five hundred million plus; $512 million.

The CHAIRMAN. Let me just ask this philosophical question. If it is deemed appropriate to charge the pharmaceutical companies and the device manufacturers these user fees, as it apparently has been by this administration, because they are the beneficiaries, why not charge them the full $500 million budget? Why are we just considering 20 percent of it?

Mr. BENSON. That is a very good question.

The CHAIRMAN. I thought so, too.

Mr. BENSON. I have talked to manufacturers of various sizes, and one could make an argument for a very different structure; but I think the rationale behind this is that the prime value of an approved product accrues to the manufacturer who comes in with that application; therefore, that manufacturer should pay for that.

I think that one could philosophically speculate over charging registration fees for everyone whom the agency is responsible for regulating, but that is not the proposal before us.

The CHAIRMAN. Just in the bosom of the lodge here, do you like this idea?

Mr. BENSON. I did not understand the question, sir. [Laughter.]

The CHAIRMAN. I promise I will not tell Frank Young or Dick Darman or anybody. Just tell me very confidentially here how you feel about it. [Laughter.]

Mr. BENSON. Could I talk to you afterward? I would be glad to do that. [Laughter.]

The CHAIRMAN. Jamie Whitten asked FDA a question over on the House side. Who testified over there? Did you?

Mr. BENSON. I was there with the Commissioner.

The CHAIRMAN. Dr. Young testified over there?

Mr. BENSON. Yes, he did.

The CHAIRMAN. I understood in response to Jamie Whitten's question of what was FDA's budget request to the Department and the Department's request to OMB that $10 million was the first request, and then $15 million was the next request. It came back from OMB $100 million.

Is that correct? Did we increase about 900 percent there along the way?

Mr. BENSON. I am not clear on exactly what happened at which level of the administrative review, but I think the final line was certainly $100 million. I think we did in fact submit that following that hearing, and I think we have that if you would like to have it.

The CHAIRMAN. I have it here. I am going to go ahead, without objection, and enter this into the record, because the question was asked regarding full-time equivalents. How many FTES it would require and what was the request. I have the number broken down and I will submit for the record.

[Material follows:]

FY90 FDA BUDGET HISTORY

	Request To PHS		Request To DHHS		Request To OMB		Request To Congress	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	2,417	$166,343	2,417	$163,343	2,223	$150,891	2,129	$144,476
Drugs	3,605	268,619	3,593	264,320	3,446	269,047	3,318	249,546
Devices	1,394	91,056	1,394	88,056	1,394	90,303	1,321	89,221
NCTR	243	26,374	243	26,374	243	27,264	232	26,830
Program Management	348	32,370	348	32,283	331	32,297	322	32,598
GSA Rent	—	36,270	—	25,612	—	25,100	—	25,612
Buildings and Facilities	—	53,730	—	9,450	—	5,421	—	1,450
Revolving Fund for Cert.	45	—	45	—	45	—	45	—
Advances & Reimbursements	20	—	20	—	20	—	20	—
Service and Supply Fund	120	—	120	—	120	—	120	—
TOTALS	8,192	$674,762	8,180	$609,438 1/	7,822	$600,323 2/	7,507	$569,733 3/

1/ Includes $10.1 million derived from user charges.
2/ Includes $14 million derived from user charges.
3/ Includes $100 million to be derived from user charges.

NOTE: All columns have been adjusted to reflect the impact of requests during the process for blood bank surveillance, the generic animal drug act, the pesticide monitoring act, and to reflect the $5 million added in 1989 for activities related to drug abuse.

The CHAIRMAN. Now has the FDA given any consideration to a possible small business exemption?

Mr. BENSON. Yes, we have.

The CHAIRMAN. Incidentally, let me cover the waiver. Where do you get the authority to waive these fees for orphan drugs, for example? Is that something you are asking for in this whole proposition?

Mr. BENSON. Yes. The Administration bill included the potential for a waiver for the user fees, so right now there is no fee for an orphan product. In fact, it kind of goes the other way. We are in some cases giving contracts and grants for the development of orphan products as well as other incentives.

The CHAIRMAN. Mr. Benson, that is one of my primary concerns. I have been involved in medical issues ever since I have been in the Senate, and one of my concerns always is orphan disease where maybe only 5,000, 10,000 or 15,000 in the United States are afflicted, and the economic incentive to do the research is simply not there.

Is it also not a fact that the Government actually funds most of the research for orphan drugs?

Mr. BENSON. I cannot give you specific numbers for that. We have a very modest budget for contracts and grants in the orphan area. I think this year we hope to spend on the order of $5.5 million in that area. I will have to look up the breakdown for you, but between the modest amount that we have and what NIH does, I would assume that most of that research does come out of the Federal Government.

The CHAIRMAN. Do you have any idea how much NIH puts into the so-called 276 designated orphan diseases?

Mr. BENSON. I do not have it. I would be happy to look it up for you.

[Material follows:]

FEDERAL FUNDING FOR ORPHAN PRODUCT RESEARCH

The Food and Drug Administration (FDA) is the only specific source of federal funds for the development of products to treat rare diseases. The Agency's Office of Orphan Products Development maintains a grant program to support clinical studies needed for the approval of orphan products. In fiscal year 1988, the FDA funded $4.5 million for these studies. In fiscal year 1989, the agency estimates that the program will expend $5.4 million. FDA is unable to determine the amount of money allocated to orphan drug research by the National Institutes of Health.

There are over 5,000 rare diseases. As of August 31, 1989, FDA has approved 299 products for rare disease indications for which the sponsor has requested orphan product status.

The CHAIRMAN. I guess that is orphan drugs, is it not?

Mr. BENSON. That is the number of drugs that we had designated as orphan. So they would then be eligible if they carried through to approval for the various special considerations that the Orphan Drug Act provides.

The CHAIRMAN. That is one of the places where the good old free enterprise system fails us.

Mr. BENSON. Yes, sir.

The CHAIRMAN. There is a lot of pain and suffering in this country. If it were not for the Government actually funding, doing something about those diseases since it is just not economical for the big companies to find a cure, nothing would ever happen.

Mr. BENSON. I agree with that.

The CHAIRMAN. Now, to get back to the question on small business exemption, I do not know whether you can do that. Have you thought about it?

Mr. BENSON. We have thought about it. We have reached no conclusions. I think we would prefer before we spelled out anything to look at not only the legislation that is finally approved but also the intent of Congress in terms of how to handle such a waiver. Then, of course, following the enactment we would need to put forth a proposal and have notice and comment to make sure we had adequate input from people around the country on how to proceed.

Conceptually, though, I think we acknowledge that is an appropriate step; that is, to have some system of exemptions in place for orphans and perhaps for others.

The CHAIRMAN. Mr. Benson, on food and color additives and things that people might want to do to make their product a little more attractive for the market, I think you ought to charge whatever your cost is on that. Not percentage, but the total cost, because that is something where most of the time the consumer is getting nothing. He is probably being entrapped a little bit to buy a product simply because it looks better.

All you are doing is making sure that whatever they put in it to make it look better is not harmful to one's health. So it is obvious that the company gets the benefit in a situation like that. There may be some other things that FDA does that fall into the same category.

I am still troubled. I am not worried about a giant company going bankrupt because of these user fees, but I am worried about some of the small businesses. They tell me that 90 percent of your new drug applications come from pharmaceutical companies with fewer than 500 employees. Now in this particular business, 500 employees is a lot, I think. When I think about small business, I am thinking about the guy in Little Rock with 15 employees, for example, or 100 employees.

Senator Lott.

STATEMENT OF HON. TRENT LOTT, A U.S. SENATOR FROM THE STATE OF MISSISSIPPI

Senator LOTT. Thank you, Mr. Chairman.

Mr. Benson, let me explore just a little further the line of questioning that the Chairman was asking you about, the business exemptions.

I guess the bill that we are referring to here is this H.R. 2482, the Madigan Bill.

Does it have a small business exemption of any kind?

Mr. BENSON. Yes, sir, it does.

Senator LOTT. What is that?

Mr. BENSON. Tom, do you have the exact language there?

Mr. SCARLETT. It does not specifically refer to small businesses. It says that there shall be provision for reduction or waiver of fees in exceptional circumstances in the public interest.

Senator LOTT. So what you are suggesting here is that you would want under the legislation authority to establish a small business exemption which I assume would have general applicability, or would you want the authority to make a determination on a case-by-case small business basis?

Mr. BENSON. I think the Administration bill was based on a case-by-case basis. Of course, whatever legislation was enacted is what we would go by.

Senator LOTT. I would be concerned about that. It looks to me like you would need some general guidelines that would be applicable and not just do it on a case-by-case basis because then, you know, the determination is quite often in the hands of a person without any real guidelines or, as we would say up here, a bureaucrat that might not be sensitive to some of the considerations that we think should be considered.

Mr. BENSON. Again, I think we would be guided by the content of the legislation and also perhaps in some cases even more importantly by the intent of Congress as a result of the hearing language and so on.

Senator LOTT. You know, again referring back to some of the questions the Chairman started off asking, I was just asking myself or wondering what precipitated all this. Why now? Is it strictly budgetary considerations, or is this something that needs to be done on some fairness equivalency basis or something?

Mr. BENSON. I think the prime motivation on the part of the Administration is fairness.

Senator LOTT. Fairness?

Mr. BENSON. Fairness.

The CHAIRMAN. You had a little wry smile across your face when you said that.

Senator LOTT. I asked him to repeat it.

Mr. BENSON. No, I didn't mean to imply anything other than the answer. I was going to add that from our perspective the budget certainly looms heavily, and I think with the budget deficit and the funding in not only that program but other programs in Government, we have to look for other solutions because we simply are slipping in terms of what we can provide and what the law does require us to do not only in the product approval area but in other areas in terms of delivering what Congress intended. So that certainly is a concern of the Agency.

Senator LOTT. You said in your testimony you wanted the Agency to be user friendly.

Mr. BENSON. Yes, sir.

Senator LOTT. When you say user, you are referring to the companies, are you not?

Mr. BENSON. Yes. User-friendly.

Senator LOTT. I would not think this legislation is going to make you more user friendly.

Mr. BENSON. I would agree that that is arguable. My point was that we have tried to reach out in many ways to make not only the approval process but our whole regulatory process more understandable by the industry such that we can have better informed clients, if you will.

Senator LOTT. You also referred in your testimony to the language that you were responsible for the safety and health of the Nation or something to that effect. I think that is true, and so I wonder why it should not be the responsibility of the Nation to pay. These companies are not asking for you to do what you do. They do it because they are required to do it.

So that is why I have problems with the user theory concept in its entirety. Maybe I am not asking for an answer there. I am just making a statement. So let me switch to a couple other questions.

I think everybody knows that even the large producers of pharmaceuticals will tell you that a large percentage of innovation in the market comes from the small business, small companies; yet, this is clearly going to put additional costs probably on small businesses. Of course, you get into a debate over what is small business and what the exemption is going to be, but is there any doubt that this would add additional costs to even middle sized pharmaceutical companies? It therefore is going to be a further discouragement to the innovation that you really need, particularly in a field like pharmaceuticals.

Mr. BENSON. We will never know until an evaluation is done following a user fee scheme what the net result is. I think that if we could get beyond simply making up the $100 million deficit, if you will, and augment the product approval resources of the Agency by speeding up that process, that the cost to the company could be reversed. You might actually have a surplus as a result of additional resources that the Agency could obtain from user fees to speed up the product approval process.

Again, we will not know that until something happens.

Senator LOTT. We do not know that that is going to be the result; therefore, there is no reason to assume that you are going to be able to speed it up because you may not get more money.

Mr. BENSON. That is certainly valid.

Senator LOTT. Do you have any information about the percentage of small companies that are currently producing these pharmaceutical products and devices? Do you have any numbers, large versus small?

Mr. BENSON. I think Senator Bumpers mentioned that 90 percent of the device industry is made up of companies with fewer than 500 employees. I do not think the breakdown is quite that dramatic in favoring the small manufacturer in the drug area. I do not have those figures. We do have them for devices. I think it would be not so dramatic in the drug area.

Senator LOTT. What factors would you take into consideration in setting the fee that a company would pay?

Mr. BENSON. Again, the fees have not been set, and I do really want to emphasize that. The numbers that the Senator mentioned were rough estimates. There are a lot of questions that need to be answered, but the way we did it was simply to look at the cost of the product approval for whatever category we were talking about and simply divide that by the number of product applications that came in.

Senator LOTT. I know Senator Burns has some questions. I just would like to say I appreciate your very difficult position. We are glad to hear your testimony. I have a lot of reservations about it. I personally am opposed to this proposal, and certainly if the legislation does move forward I would think the Small Business Committee Members are going to want to be very much involved in it.

Thank you.

Mr. BENSON. I certainly understand that. Thank you.

The CHAIRMAN. Thank you, Senator Lott.

Senator Burns.

Senator BURNS. Just a couple of questions. Thank you, Mr. Chairman. I want to express the same feelings that our Chairman expressed and also those of Senator Lott.

I guess I should ask you this, and maybe I do not have a true understanding of it, and you can enlighten me. Why do we have the FDA?

Mr. BENSON. Simply put, it is to assure safe and in some cases effective products getting to the market.

Senator BURNS. The American people thought it was to their benefit to have this agency so that they do not get dangerous drugs or drugs that do not do what they are supposed to do. We know the cost of developing those drugs. When you say businesses smaller than 500 employees, 500 employees is a lot of employees where I come from, yet they have found a few things out.

Do companies get a tax credit for the development of so-called orphan drugs?

Mr. BENSON. That is right. One of the benefits that accrue to approval of a drug that has been designated an orphan drug is a system of tax credits. That is true.

Senator BURNS. That tax credit is in place, been codified, and we do not have to deal with it as in other areas that we have our R&D programs; is that correct?

Mr. BENSON. I think so, yes.

Senator BURNS. OK. You said a while ago in answer to the question why you would charge it, and you said, "In fairness." I want you to explain why you would propose legislation such as this in a sense of fairness.

Mr. BENSON. The concept as I understand it of fairness, as you ask, is that since the primary benefit of getting a product approved accrues to the sponsor of that product or the manufacturer of that product, then it is "fair" that that manufacturer should reimburse the Government for the review of that product.

Senator BURNS. I have no other questions, Mr. Chairman. That kind of shut me off at the gap right there. Thank you very much.

Thank you, Mr. Benson.

The CHAIRMAN. Thank you, Senator Burns.

Senator Levin has just joined us.

Do you have any questions of Mr. Benson?

While we are waiting for Senator Levin, Mr. Benson, has anybody done a study as to whether or not these fees will be partially or wholly passed on to the consumer?

Mr. BENSON. I know of no study that has been done.

The CHAIRMAN. It would be logical to assume that some of it would be, would it not?

Mr. BENSON. I think that is really a function of what the ultimate sales volume of a given product is. If that sales volume is large enough, the fee would probably be not much more than a ripple; but certainly logic dictates that if it is not very large and the fee is relatively large, then that is going to be passed along.

The CHAIRMAN. Without going through a lot of convoluted rationales here, let me just say that companies are like bankers. They try to maintain a certain spread so when they go before their stockholders every year they can report sales were up and therefore profits were up. I think we could reasonably expect somewhere between $50 million and $100 million of this, maybe more, could be passed on. I could make an argument that there would be more passed on to the consumer.

Then the next point is since Medicaid and Medicare and WIC and all the State public health offices in the United States pay for a very large share of the health care costs in this country, including drugs, it would be fair to assume that the Government is going to wind up picking up a good portion of this tab. So we are just sort of robbing Peter to pay Paul.

Mr. BENSON. I think that is a good point. I would say that it does zero in on the population and the benefits if it were passed along. No matter who it was picked up by, whether third-party carriers or the Government, it would at least zero in on those people that specifically benefited.

The CHAIRMAN. Let me make two other quick points. No. 1, the elderly are the ones who are hardest hit by drug costs. We are not here to defend the elderly. We are here to defend small business; but we all defend the elderly. They are the ones who are the hardest hit by drug costs in my opinion.

I might also say that it is the people who are dependent upon Medicare and Medicaid, the two programs that pay a lot toward hospital and doctor bills but not very much on drug bills. So there are a lot of people, particularly the elderly, who are going to be absorbing probably an inordinate share of these user fees.

That is the domino effect. I suppose you can make arguments on the other side, but I know that there is some validity to that argument.

Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman. I appreciate——

Senator BURNS. Would the Senator yield for a moment? I have an opening statement. May I have that submitted for the record?

The CHAIRMAN. Senator Burns' statement will be submitted for the record.

[The prepared statement of Senator Burns follows:]

SMALL BUSINESS COMMITTEE
SENATOR CONRAD BURNS
JUNE 13, 1989
"FDA USER FEES"

Mr. Chairman,

Thank you for holding this hearing today. I will be brief in my opening comments.

I look forward to hearing a small business perspective on this issue. From the material I have read so far, it looks as though the proposed user fee could have some rather negative side effects. The SBA has made some valid criticisms of this proposal, and I look forward to hearing FDA's response to them.

I personally question the proposal because I believe that businesses--especially small businesses--should not be taxed on innovation. The costs of marketing a new drug or device is high enough, adding more costs to the approval process only discourages advancement. It may also drastically hinder a small firms ability to compete.

I agree with the quote cited from the Institute for Research on the Economics of Taxation that it is (and I quote) "a remarkable position for a government to take" that "the government can choose to impose regulatory constraints on an activity...and then assert that the regulated parties benefit by not being drummed out of business."

Mr. Chairman, this is just another example of federal government over burdening small business. I hope we can take steps to "fix" this proposal, and others like it in the future.

Senator BURNS. Thank you very much. I am sorry.

STATEMENT OF HON. CARL LEVIN, A U.S. SENATOR FROM THE STATE OF MICHIGAN

Senator LEVIN. Thank you, Mr. Chairman. I have some questions that impact on user fees somewhat more broadly than small business but certainly include small business.

The first question is whether or not the FDA has done an analysis of the effect of user fees on public health; for instance, the impact of any user fees in delaying the introduction of new drugs or food safety products, and so forth.

Has that kind of a study been made?

Mr. BENSON. I do not believe it has in terms of user fees impact. That is the business we are in, to look at the impact of drugs, food additives, devices or whatever, on public health.

Senator LEVIN. Could a user fee have the effect of delaying or even prohibiting the introduction of a new drug or food safety product? Is it possible?

Mr. BENSON. I think that is a good question, and I would have to answer that it is possible; that it could be a negative incentive of a product being introduced.

Senator LEVIN. Mr. Chairman, you may have covered this already. Qn the small business issue, has a study been made on the disproportionate impact of user fees on small businesses? Do you have a written study in hand?

Mr. BENSON. No, we do not.

Senator LEVIN. Has this been covered, Mr. Chairman?

The CHAIRMAN. To some extent.

Senator LEVIN. As to whether or not they are going to make such a study?

The CHAIRMAN. We talked about their asking for a right of waiver for applications on orphan drugs and small businesses.

Senator LEVIN. Then we would not need the study because you are already——

The CHAIRMAN. But the study has not been done.

Senator LEVIN. Well, you have reached the conclusion that you are going to ask for a waiver because you believe there is such an impact and we would not need such a study.

Is that the FDA's conclusion?

Mr. BENSON. I think, if I could state it this way, there is concern on our part for the impact on small business and on orphan product sponsors sufficient that we have a clause in the proposal that would allow for exemptions under exceptional cases.

Senator LEVIN. Would that apply across the board to small business, or would that be a case-by-case approach?

Mr. BENSON. As it is written and as I understand it, it would be on a case-by-case basis at this time.

Senator LEVIN. In that case it might be useful to have a more generic study. Is that feasible, or is that a big deal?

Mr. BENSON. I guess it depends on how in depth you want to get.

Senator LEVIN. If the Chairman approves of this, could you get back to the Committee with at least the design of a possible assess-

ment of such an impact without doing it right now? Just tell us what would be involved in making that kind of an assessment.

Mr. BENSON. Certainly.

Senator LEVIN. Would that be all right, Mr. Chairman?

The CHAIRMAN. It certainly would. It would be highly desirable.

Senator LEVIN. Thank you.

[Material follows:]

DESIGN SPECIFICATIONS FOR:

A STUDY TO ASSESS THE PROBABLE ECONOMIC IMPACT ON SMALL BUSINESSES OF USER FEES TO RECOVER FDA'S COSTS FOR REVIEWING VARIOUS MARKETING APPLICATIONS REQUIRED BY THE FEDERAL FOOD DRUG AND COSMETIC ACT.

Introduction

An acceptable system of user fees to recover FDA's costs for reviewing marketing applications must be as fair and equitable to all applicants as possible. As a general rule, this means that the fee for any particular application should correspond reasonably with FDA's actual costs for reviewing the application. In theory, this requirement can be satisfied for all types of marketing applications by stratifying each type of application into sufficiently detailed sub-categories which correspond to distinctly different levels of review effort by FDA. Assuming this optimal structure is achieved, however, there remains a possibility that some small businesses will face fee structures that may adversely affect their ability to compete in new markets or discourage their research into new products that would have been viable in the absence of user fees.

Purpose of the Study Design

As its first objective, this study design must present a method for collecting relevant data and analyzing it with sufficient rigor to determine the likelihood that an otherwise equitable system of user charges for FDA marketing applications may impose significant economic burdens on small businesses. The method should recognize a market approval fee as an incremental cost to a series of variable, often uncertain, and time-consuming expenditures for new product development. The financial significance of such fees, therefore, is likely to depend in large part on the research environment of the particular sponsor. Thus, the threshold at which a fee becomes "significantly burdensome" might be expected to vary by type of application (e.g., more for a new drug application than for an ANDA or a 510k application). Its significance may also depend on the financial situation and market history of an individual sponsor. A user charge for approval of an innovation financed by "sweat equity" and the life savings of a new entrepreneur may pose a more significant burden than the same fee for approval of an improved model in a successful product line of an established small firm.

As its second objective, this study design should assemble information that will assist in the formulation of a fee structure that will balance the goals of (1) a fair and equitable fee for each applicant, (2) minimally burdensome fees upon small business applicants, and (3) reasonable administrative

efficiency. In satisfying its first objective, the study will assemble considerable data concerning the actual costs of FDA's application review for certain small business applicants. This information can provide valuable insights into the best means of balancing the three aforementioned goals of an optimal fee structure. Such a system may necessarily include a myriad of structural details such as different fee categories for various types of applications (e.g., large, medium and small classes of NDAs), and rules for the timing of fee payment (e.g., full payment upon initial submission vs. partial payments allocated across anticipated amendments or resubmissions). For larger firms, the financial implications of imperfections or administrative compromises in these design features may "average out" over the course of submitting many applications, but for smaller firms this prospect may be less consoling and less realistic. Thus, the small firm perspective is probably the best vantage point from which to consider the trade-offs between the three goals of any acceptable fee structure.

Study Design

This study consists of three distinct phases. The first is identifying the subset of various marketing applications sponsored by small businesses. The second step is measuring the level of FDA effort expended to review each type of these small business marketing applications (SBMAs). The third step is investigating the research, development and market introduction expenses of sponsors of SBMAs so that the size of the fee determined in step two can be put into perspective with broader product introduction expenses. Each of these steps are discussed in detail below.

1. Identify the set of sponsors of marketing applications that can be categorized as small businesses.

The first phase of this study is designed to identify the number and character of small business sponsors and the number and frequency of their SBMAs. It is accomplished in the following sequence of steps:

a. Develop lists of recent sponsors of the various marketing applications for which FDA may propose user fees. The types of applications would include but not necessarily be limited to NDAs, 510ks, PMAs, biological licenses, food and color additive petitions. These lists should cover the most recent applicants possible while providing a sufficiently broad time interval to identify the frequency of submissions from individual sponsors. A three to five year period through 1988 would satisfy these dual requirements. These data are available from various FDA files and information systems.

b. Collect data on the sponsors listed in Step 1a to develop an industry profile of sponsors of various marketing applications and to permit tentative identification of small businesses on

these lists. These data will include information about the number of employees, sales and profits of these firms. This step must include the acquisition of business information on a wide assortment of foreign as well as domestic firms. While international data bases may provide information on most firms in the major industrialized nations, special efforts may be required to gather comparable data for third-world firms, e.g. Ik Kyo Chung and Steviaside Kebaudiana Making Factory.

c. Develop a set of decision rules to classify several special categories of application sponsors into relevant firm sizes for purposes of user charges. The primary criterion for classification as a small business is a firm's number of employees, but this can be an inappropriate or unavailable statistic for some sponsors of FDA marketing applications. These situations can be categorized as follows:

(1) Intermediary Sponsors: Firms sometimes use an agent or representative in their submissions to FDA. Examples include:

The Belgian Embassy
Center for Regulatory Services
Regulatory Assistance Corp.

In these situations, the original sponsor must be identified and described.

(2) Non-Profit or Trade Association Sponsors: Some of the sponsors in this group may simply be additional examples of "intermediaries", but others may be serving on their own behalf (e.g. universities) or on behalf of the public (e.g. public interest groups):

Agriculture Canada
American Mushroom Institute
Calorie Control Council
National Soft Drink Association
Nebraska Department of Economic Development
Rutgers University
Sierra Club
Society of the Plastic Industry
University of Perugia

In these situations, some rules for sponsors representing others and the fee status of non-profit entities will be desirable.

(3) Individual Sponsors: Some marketing applications are sponsored by individual persons without any identification of their organizational association. They may be either individual entrepreneurs or undeclared agents of commercial enterprises. The same type of decision rules developed for situations in

paragraphs (1) and (2) above will need be adaptable to these individual sponsor situations.

(4) Domestic Affiliates of Foreign Firms: Many foreign firms use domestic affiliates or subsidiaries to sponsor marketing applications. When these include the name of the foreign parent, they are easily associated with the parent as the following examples illustrate:

Fujisawa Pharmaceutical Co. Ltd.
Medicor USA Ltd.
Nordisk-USA
Yamoto USA, Inc.

Other application sponsors are less easily recognized as domestic affiliates of foreign firms as the following examples illustrate:

MCI Optonix (Mitubishi)
Dornier Medical Systems (Daimler Benz AG)
Pacific Hemostasis Labs (Fisons PLC)
Horiba Instruments Inc. (Hitachi)

Commercial data sources show each of these eight US corporations to have fewer than 100 employees, thus technically qualifying as a small firm on the basis of employee count. Obviously, the financial relationship of these US corporations with their parent entities may vary from firm to firm. Decision rules for the small business status of these firms must necessarily be sensitive to factors other than employee counts.

(5) Licensees and Joint Ventures: In the preceding examples of affiliates, the relationship of a possibly small firm with a larger foreign firm was either obvious or determined from commercial data sources, but a far larger number of situations exist were a small firm files a marketing application on behalf of a joint venture or license arrangement with a large firm. This situation is particularly common in the biotechnology field. These relationships are highly variable with regard to the financial investment and risk of the smaller partner. The small business status of these situations will demand special attention to establish the scale of the commercial resources behind a given joint venture application.

The results of the efforts in Steps 1a, 1b, and 1c will yield a list of bona fide small businesses submitting the various types of marketing applications to FDA. The listings will include frequency distributions of submissions, and sub-groupings of the small business sponsors submitting various applications.

2. Measure the level of FDA effort expended to review each type of small business marketing application.

Estimate the costs of FDA handling, processing and reviewing each type of SBMA. This step would include:

a. Using appropriate sampling techniques, select a representative sample for each type of SBMA submitted to the agency.

b. Collect data which would measure the following for each sampled SBMA:

(1) the number and general category of employees (e.g. professional and administrative, technical, clerical) that log, process, review, file and respond to SBMAs,

(2) the amount of time spent by each category of employee in reviewing and processing each SBMA, and

(3) overhead costs allocated to the SBMA review process.

c. Based on data collected in 2a and 2b, develop estimates of FDA review costs for approval for each type of application.

3. Collect information from sponsors of SBMAs to estimate their research, development and market introduction expenses, and assess the financial impact of user fees upon these expenditures.

This phase would include the following:

a. Stratify the sponsors of SBMAs by type and select a small but representative sample of applicants for individual cost analyses.

b. Collect cost data for bringing a new product to market among the sample of SMBAs developed in Step 3a.

c. Compare the impact of user fees developed in Step 2c with the research and development expenditures identified in Step 3b and assess the likely economic consequence of this increase in expenditures upon the small firms.

This overall three step process should be accomplished for each type of marketing application for which a fee might be proposed so that the distinctive settings of different industries and regulatory requirements can be analyzed individually to assess the likelihood of significant burdens on small business applicants from marketing application fees.

Skill Requirements

The execution of this study design will require persons with a combination of skills in financial analysis, cost accounting, economics, survey statistics and public policy analysis. Although some of the data used in this study will be readily available from FDA application lists and commercial business data systems, the study itself must assemble very essential information from raw data concerning the cost experience of small firms in developing new products and FDA's costs for reviewing their SMBAs. Access to this proprietary financial data will likely require a special atmosphere of mutual cooperation and trust between the persons conducting this study and the firms voluntarily sharing their financial data. The participation of intermediaries, such as trade associations or academic institutions, may be required to gain access to the necessary R&D cost data.

The CHAIRMAN. In that connection, Mr. Benson, do you know, for example, when somebody files an application of any kind with FDA, the application includes information which tells you whether or not that business is small business according to an FDA definition?

Mr. BENSON. I do not think we do. Before I give you a definitive answer I would want to look at each of those.

The CHAIRMAN. You do not know which of your applications come from what we call small business, then, do you?

Mr. BENSON. As a matter of fact, we talked about it this morning, and I was curious about the point myself. I do not know whether we got an answer or not? Did we?

I do not think we got an answer, but we could very easily do that especially in the device area. I think it would be worth looking at. We could simply look back over the last year or couple of years worth of approvals, and I think we would know whether they were small business or not. It is not that big of a deal.

The CHAIRMAN. If you could supply some of that information along with the information Senator Levin just requested, that would be helpful to this Committee.

Mr. BENSON. Thank you. I would be glad to do that.

[Material follows:]

Product Approval Applications Submitted to FDA by Small Businesses

The Food and Drug Administration (FDA) receives thousands of applications for marketing approval of various products from regulated industry every year. FDA does not require information about the size of the firms submitting these applications. Of course, size of the firm would provide a rather imperfect indication of an applicant's financial capacity because of the prevalence of corporate interrelationships such as subsidiaries, joint ventures, license arrangements and cross ownership in the industries regulated by FDA. Nevertheless, we have examined 300 recent applications for medical devices (including both premarket approval applications (PMAs) and 510(k) applications) and investigated the number of employees in the firm listed on these applications. Small business submissions were identified using the standard definition adopted by the Small Business Administration, that is, one that has 500 employees or less and that is not dominant in its field. The following statistics are estimates based on the information available on the firms at the time.

Out of 100 Premarket Approval Applications submitted, approximately 80 percent of the firms qualified as small businesses.

We reviewed a total of 200 510(k) submissions from two different timeperiods to take into account various submission patterns. In the first sample of 100 submissions, 80 percent of the firms were small businesses. In the second sample of 100 submissions, approximately 70 percent were small businesses.

These statistics indicate that approximately three out of four or 75 percent of the submissions by the device industry were from small businesses. We believe this is an accurate reflection of submissions to FDA by the device industry. However, additional research would need to be accomplished before the Agency could accurately assess the percentages of small business submissions received in other product approval areas. Furthermore, should another definition of small business be chosen, the numbers might be very different. Discussion among Senators on the Small Business Committee revealed at the hearing that a number of different definitions of small businesses might be acceptable to the Committee, and that those definitions might have a lower threshhold of fewer than 500 employees.

The CHAIRMAN. Mr. Benson, we thank you and all of your staff who accompanied you for being with us today. It is helpful to us to have the benefit of your thinking.

Mr. BENSON. Thank you.

The CHAIRMAN. Our next witnesses are Mr. J. Bert Bunnell, Bunnell, Inc., Salt Lake City; Mr. Larry Blansett, Blansett Pharmacal, North Little Rock, AR, and Mr. David Holveck, Intro Diagnostics, Malvern, PA.

Mr. Bunnell, Senator Hatch was here to present you to the Committee and decided that we were going to spend too much time and he had other fish to fry. Is that correct?

Mr. BUNNELL. Evidently.

The CHAIRMAN. Well, we are happy to receive you anyway.

Is Mr. Blansett here? Please come up, Mr. Blansett, and have a seat.

We are taking the witnesses in two panels this afternoon to save a little bit of time.

Mr. Holveck, you are also on the second panel.

Do you ever get mail that is addressed to Malvern, AR, or does the zip code cure that problem? You did not even know there was one, did you?

Mr. Blansett, who is seated on your left, knew it, did you not, Larry?

Mr. BLANSETT. Absolutely. It is about 45 minutes from Little Rock.

The CHAIRMAN. Mr. Bunnell, please proceed with your testimony.

[Material follows:]

Introduction
Of
J. Bert Bunnell, Ph.D.
June 13, 1989
Committee on Small Business

Mr. Chairman, I would like to thank you for the opportunity to introduce Dr. Bert Bunnell to you and the members of the Committee on Small Business. Dr. Bunnell is a third generation small business man. He is a graduate of the University of Utah and received his doctor of science from the Massachusetts Institute of Technology in 1972. He formed his own company, Bunnell Incorporated in 1980.

Bunnell Incorporated employs approximately 19 people in Salt Lake City and became the first company to receive FDA approval of a high frequency ventilator in 1988. The Life Pulse High Frequency Jet Ventilator is now gaining rapid acceptance as a superior technique for the treatment of infants in respiratory distress.

Mr. Chairman, I know that you join me in looking forward to Dr. Bunnell's testimony. He will bring valuable insight to this Committee regarding user fee proposals impact on small business.

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STATEMENT OF DR. J. BERT BUNNELL, PRESIDENT AND CEO, BUNNELL, INC., SALT LAKE CITY, UT

Dr. BUNNELL. Thank you. I really appreciate this opportunity.

I was a biomedical engineer 17 years ago working as a research fellow in pediatrics at Massachusetts General Hospital in Boston, and I discovered a vicious cycle going on in their newborn intensive care unit. In order to keep premature babies alive they were hooked up to breathing machines, which we call ventilators, which simulated normal breathing.

As the babies got worse we had to use higher and higher pressures in order to keep their lungs inflated. These higher pressures created leaks in the lungs. They would pop the little alveoli and create tears in the fragile lung tissue. The more the lungs were damaged, the higher the pressure that had to be used. In this vicious cycle, if it did not end in death for the infant, we ended up with babies who had chronic lung disease for the rest of their lives.

This vicious cycle had a very high cost to all involved: The babies, those taking care of the babies, the parents, and society for taking care of the pulmonary cripples. I even had one personal friend commit suicide because of the impact that it had on his family.

My mentor in those days, Dr. Dan Shannon at Massachusetts General, and I developed a concept that we thought could allow us to break out of this vicious cycle. We observed that dogs could pant with very little effort, and they did that in order to maintain their body temperature, breathing very shallowly.

We considered that it may be possible to breathe babies in this fashion in order to regulate their oxygenation. We thought that panting may be a means to provide for better ventilation without having to use so much pressure. So breaking out of that vicious cycle has been kind of the centerpiece of my work for the last 17 years.

The legislation that you have before you now represents to me a potential new vicious cycle that we could get into, so I just want to give you a little background about how I spent the last 17 years and then let you know what I see on the horizon with this new legislation.

I spent just about 3 years in Massachusetts General working on this new technology, and then I realized I had to leave academia and get into industry in order to really commercialize the idea. So I spent the next 5 years with two major companies trying to produce a product, and 10 years ago I started my own company in Salt Lake City.

In the major corporations I lost my support when I could not commercialize the product within 2 years. The companies I worked for had very short-term outlooks in terms of what they needed for getting a return on their investments.

I was only able to start my new company through a very special program at the University of Utah that was originally funded by the National Science Foundation called the Innovation Center. That program has now been privatized.

In anticipation of becoming an entrepreneur, I was counseled that it would be a long tough road; that I would have a low or no

salary for a number of years; that there would be quite a strain on my marriage and my family; that I would probably have to put my house up for collateral for loans; and that FDA approval would be required.

All of this came true in spades. It has taken us now 9½ years to reach the level of break even. I went 4 years with no salary. I did not lose my house or my marriage, but I do not know when my teenage son will forgive me for not always being there.

The CHAIRMAN. You are among friends here. We are all parents. We understand.

Dr. BUNNELL. Thank you.

Well, the FDA approval part of this ordeal turned out to be a many splendored event. There were mountains of paperwork and some real gut-wrenching arguments over what constituted proof of safety and efficacy. In the end we reached a common ground, and I feel very good about the process.

I know that there are many ways that the FDA could have done a better job and many ways that I could have done a better job and that we could have gotten the task accomplished sooner; but all in all, I feel that it is a very worthwhile process.

Now that we have proof that our device is safe and effective, it appears to save about half of the babies that were dying of the respiratory complications of their prematurity, and it also appears to greatly reduce the survivors' time in the hospital and improves their outcomes dramatically. We are still continuing to seek data that will prove these points.

Meanwhile, we finally have sales. We introduce three or four new hospitals to this technology 1 month ago even though we have only enough funds to have two part-time sales representatives working independently out of Allentown, PA, to sell the device. So most of our sales come from "word of mouth."

Our sales have more than doubled since we received this FDA approval, and we are about to close a deal where we are finally able to get out of debt and can really start taking advantage of this opportunity.

So where is the vicious cycle that I see? Our profits from the sale of this new product are being used to grow a company, to build the manufacturing and the marketing capabilities to allow us to really effectively commercialize the technology.

We have competition that is partly domestic and partly Japanese, and we need new products to grow. Now we are in the position that a lot of the larger companies are in where we have a number of choices, and in the choices of which product to do next we have to weigh out the costs and potential benefits for developing those products.

As we look at those products that require the Class 3 FDA approval like we have just gone through, we see again that it is a long, hard road, that we will have to keep our expenses down, maintain low salaries, do without a lot of things. There is going to be a strain on our marriages and our families, and FDA approval is required.

So I think this is not an issue that just affects small companies. I think it affects every company, and what it really affects is the de-

velopment of new technology, new products, exciting things that do not now exist.

So the vicious cycle that I see is that if you adopt these FDA user fees, it will definitely contribute to fewer new products and fewer new companies. That result will lead to lower United States output. Lower domestic output will lead to more foreign products in our country, more foreign competition and greater budget deficits. As the budget deficits go up, there will be a demand for higher and higher user fees, and the cycle will be complete.

So I see this proposal of user fees as being a tax, a tax on innovation and a tax that will weigh particularly heavily on those of us who can least afford to pay it. It is not just the small companies. It's the champions of new technologies, and the people who really want to contribute in a bigger way.

Thank you.

[The prepared statement of Dr. Bunnell follows:]

STATEMENT BY

J. BERT BUNNELL, PhD.

PRESIDENT & CEO

BUNNELL, INCORPORATED

BEFORE THE

COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

JUNE 13, 1989

22-152 0 - 89 - 4

Brief Description of Bunnell Incorporated

Bunnell Incorporated designs, manufacturers and markets life-saving, cost-saving products for use in supporting and monitoring the respiration of critically ill patients. The company's initial focus has been on providing newborn infants, especially prematurely born infants, with a unique new ventilator or breathing machine that assists their breathing through the injection of up to 11 tiny spurts of oxygen and air per second into their lungs via a tube inserted into their trachea.

These high velocity, low pressure, "jets" of gas create a condition not terribly unlike the panting of a dog. Bunnell's Life Pulse High Frequency Jet Ventilator is rapidly becoming accepted by the medical community as a gentler and more effective means of treating these tiny patients. It appears to save about half of the infants that are now dying as a result of their respiratory distress.

Our company hopes to be able to prove that the Life Pulse is also responsible for sending sick infants home earlier, saving society the thousands of dollars a day of care that these little patients require to stay alive. Once home, the prognosis for most of these infants to lead full and productive lives is quite high.

Thus, the investment of $23,900 for a Bunnell Life Pulse is well worth the money.

I founded Bunnell Incorporated in 1980. We presently employ 19 full-time and four part-time people in Salt Lake City, Utah. As President and Chief Operating Officer, I oversee research and development, marketing, and serve as a clinical advisor, teacher, and trainer for our customers. Our other managers include a vice-president and general manager who oversees financial matters and operations, and a marketing manager who oversees sales, advertising, public relations, customer service and training. We also have a director of research and development who designs, develops, and documents all our products, and controller who is responsible for the accounting and human resources and employee benefits.

Description of Bunnell's Product Development Process

Our development of the Life Pulse High Frequency Ventilator followed a process typical of FDA Class III medical products that are life saving and/or use new technology. The story of the Life Pulse began in 1972 when I was conducting research at the Massachusetts General Hospital (MGH) in Boston.

Preliminary Research and Development

The development of the high frequency jet ventilation technique and the early prototype equipment that enabled clinical studies to be conducted took ten years. The project was funded initially by ad hoc research funds of approximately $300,000 contributed by the MGH and later by the two major companies for whom I worked from 1975 to 1980. Both companies cut off my research funds after two years due to the lack of predictable short-term returns on their investments. These funding policies prompted me to start my own company in 1980.

Bunnell Incorporated was founded in 1980 with the help of the University of Utah's Innovation Center, a project funded by the National Science Foundation for the purpose of stimulating new high-tech industries. With the help of the Center and funds invested by family, friends, and a few doctors and engineers who believed in our work, we began clinical trials with several prototype high frequency ventilators at five key medical centers around the U.S. in 1982. An additional $300,000 were invested in this technology through Bunnell Incorporated to that date.

Clinical Trials and the FDA Approval Process

Funding of the clinical trials was provided through sales of a spin-off product, a computerized monitor for patients on life

support equipment, and an investment by a major medical company who was interested in manufacturing disposable supplies for Bunnell's Life Pulse High Frequency Ventilator and marketing all of Bunnell's products.

We selected five initial test sites for the Life Pulse in Utah, Arizona, Minnesota, Pennsylvania, and Florida in an attempt to gain sufficient clinical data and feedback on the product and to eliminate regional biases. Our physician collaborators and I chose to apply the Life Pulse to those infants who represented the most difficult challenge then plaguing the field of newborn intensive care: premature infants whose treatment with conventional techniques had produced sufficient lung damage to the extent that they were in immediate danger of dying.

With close to one hundred infants treated by the end of 1985, we submitted 12 copies of a nearly thousand-page application to the FDA for approval of the device. It was rejected and a three-year battle for approval ensued.

The major criticism of our application was the lack of an untreated control group for comparison with the treated study patients. Our investigators and I felt very strongly that the establishment of a control group in this patient population would

be tantamount to sentencing those infants that were randomized to the control group, to death.

What began as a battle ended in cooperation as my diminutive staff, our investigators, and a handful of key FDA staffers put together thousands of pages of evidence that the Life Pulse was truly safe and effective from an expanded group of 200 desperately ill infants treated at 12 hospitals. By the time FDA approval was finally granted on June 30, 1988, Bunnell Incorporated was nearly $2 million in debt, I had gone four years with no salary, and our corporate backer and potential distributor had lost interest.

Exactly half of the original 200 infants survived to become living testimony to the value of the Life Pulse, and sales have fairly soared since FDA approval. My faithful employees and I are now digging ourselves out of our financial hole. Thanks to ongoing support of our customers and our corporate backer who agreed not to drive us into bankruptcy, the future for Bunnell Incorporated now looks quite bright.

Impact of the FDA Approval Process on Bunnell Incorporated

FDA Pre-Market Approval (PMA) certifies the safety and effectiveness of our high frequency ventilator. As such, this

approval is invaluable to Bunnell Incorporated. It did not come easily or cheaply.

Most innovative medical products are difficult to fund due the time and expense and uncertain returns involved. The FDA approval process, while well intentioned and valuable to companies affected as well as to the public, adds greatly to this time and expense.

Once the hundreds of thousands of dollars and years of research have advanced the state of the art to the clinical testing stage, companies must gain approval from the FDA to proceed. This approval is called Investigational Device Exemption or IDE approval. Only clinical data from IDE studies is considered in PMA applications.

It was ironic that while our prototype equipment was improved markedly from 1981 to 1986, and our physician investigators were becoming increasingly dependent upon the Life Pulse to rescue their dying babies, the process of gaining IDE approvals became more and more difficult. Individual IDE approvals had to be obtained for each new hospital as more and more data were requested. The time for gaining IDE approvals for our ventilator changed from 3 weeks to over 1 year. Although there were only two basic protocols being followed by each of our 20 hospitals,

the paper work involved grew from 5 pages for the first IDE approval in 1981 to well over a hundred pages in 1986.

As time dragged on for Bunnell Incorporated, our company's investors began to lose faith. The number of Bunnell employees dropped from 23 in 1983 to 7 just before FDA approval in 1988. Our major corporate sponsor dropped out and pressured me in 1986 and 1987 to either help it sell its interest in company, or sell the company altogether. We were unsuccessful in our attempts to sell either our corporate backer's interest in the company or the company as a whole because of our large bank debt and uncertainty over FDA approval of our major product. We could no longer pay the interest payments on our bank loan at the end of 1987 and our corporate backer begrudgingly paid off the bank on our behalf and allowed us to begin accruing the interest payments to them.

Bunnell Incorporated also received major financial support from its customers. Twenty hospitals and several doctors paid us for prototype ventilators (often in advance) in order to keep their investigations going and Bunnell Incorporated in business. Although these sales amounted to approximately $750,000 from 1986 through 1988, we did not violate the FDA's rule that sales of investigational products may not be made at a profit. It was quite easy for Bunnell Incorporated to be un-profitable during its years of seeking FDA approval.

Recommendations and Suggestions Concerning the FDA Approval Process

My greatest difficulties with the FDA approval process were related to:

1) slow responses to our submissions,
2) lack of appreciation for the clinical importance of certain issues, and
3) the turn-over rate of FDA personnel.

I would recommend that FDA funding and management policies be reviewed to reveal the means whereby these problems can be better handled. Specifically, I found gross differences in mandated response time limits imposed on the FDA staff for dealing with the various types of applications they have to process. For example, the staff has 30 days to respond to on IDE application and 6 months to respond to any information submitted in support of a PMA application.

Since many of our documents submitted in support of our PMA application were several hundred pages long, I sensed that certain FDA staffers were putting off dealing with these rather long and detailed submissions with ill-considered responses at

the end of their 6-month deadlines. I know that they always had a stack of much shorter IDE applications to process with much shorter deadlines to meet. Turn-over of FDA personnel cost us dearly. I considered that I would have to spend a considerable amount of time teaching FDA personnel about the fundamentals of my area of expertise given that it represents a new technology. It seemed, however, that just when I had one of the key reviewers of our submissions up to speed, he or she move on into another area of their bureaucracy.

My conversations with these people revealed a consistent story of their being over-loaded with work and constantly having to put up with characters like me who want to have their applications speedily processed. My favorite FDA reviewer even hung up on me once during a telephone conversation with her frustration over my insistence that babies were dying because of the lack of FDA approval, and her inability to get to our latest submission because of her other obligations. She lasted about a year and a half before she received a transfer to another area of the FDA.

I found the staff at the FDA to be generally quite dedicated and diligent in their work. I found only one area where I feel that a modification in the pre-market approval process might be very helpful. I think that they should use their clinical advisory panel much earlier in the application review process, and they

could visit one of the test sites to gain a more first-hand impression of what the important clinical considerations are.

We were held up for at least four months at the outset because a key supervisor at the FDA "wasn't impressed". I recall he said: "Most of your babies eventually died. If they are going to die anyway, why bother?"

I requested that the FDA staff check with their Advisory Panel which consisted of mostly anesthesiologists for feedback on some of our most basic disagreements such as the necessity for a control group in a desperately ill population. It wasn't until June, 1986, That I could finally get them to discuss our application with the Advisory Panel. I tried to arrange a meeting with the chairman of their panel at an informal meeting in Washington in February, 1986, and they threatened to have the man arrested when he arrived from Philadelphia at my invitation rather than at their invitation. He resigned from the Advisory Panel in protest.

We had three ventilators in almost full-time use only 2 hours away in Philadelphia since the beginning of 1983, and two devices in Georgetown, only 20 minutes away, since the end of 1986. It wasn't until the fall of 1987 that I finally got two FDA staffers

to visit the Georgetown University Hospital during their lunch hour to see a baby being treated with our device.

The Impact of User Fees on Innovation and Foreign Competitiveness

In our industry, smaller companies tend to be the innovators. Start-up companies frequently are founded with an exciting new technology that the founders seek to bring to market. In the eight and one-half years from our founding to FDA approval of our high frequency ventilator, our total revenues were $2.25 million. Out expenses for R & D during this period were $1.95 million or 86% of revenues. Larger companies obviously don't operate this way.

Many of our competitors, especially the large established market leaders, want no part of any product that requires Class III Pre-Market Approval. The approval process is long, arduous, and expensive. By the nature of the classification, approval is not guaranteed.

A user fee for companies seeking FDA approval is a tax. It's a tax on innovation, and it taxes those least able to pay, the small companies.

If we had been assessed a user fee during our development of the Life Pulse High Frequency Ventilator, it could have been devastating. Without this tax, I almost lost my house and my marriage, and my company is still almost $2 million in debt. I would hope that my government would be a little more encouraging to those of us who are crazy enough to pursue our dreams in spite of all the technical and business obstacles we already have in front of us.

The effect of a user fee on competitiveness with foreign companies can also be devastating. We have Japanese and European competitors who have thus far been limited in their ability to penetrate the U.S. market by their reluctance to deal with the FDA approval process. However, we also require FDA approval to sell our products outside the U.S. While we are grinding out our proof of safety and effectiveness, our foreign competitors have unrestricted sales potential in the rest of the world.

We had one competitor, a Japanese firm, supply a U.S. National Institutes of Health (NIH) sponsored study of high frequency ventilation with 100 units in 1986. This firm was able to respond to an NIH request for supplying the study with equipment even though it had no prior knowledge in the field subsequent to 1985. They were able to build a sufficient number of impressive prototypes and gain the NIH contract during the same period of

time that we were forced to lay off half of our staff due to our dwindling resources. Fortunately for our competitive position, the NIH investigators had a myriad of problems with the device during this study. In addition, the results of the study revealed that the Japanese machine, which used a different type of high frequency ventilation called high frequency oscillation, was associated with an increased incidence of severe brain and lung damage in the infants it was used to treat. Thus, we don't expect much competition from that device in the U.S. anymore.

In conclusion, a user fee for FDA applications comes across to me as a kick in the teeth. I respect and even appreciate FDA regulations, but if they need additional funding to meet their obligations, I suspect that a better source of these funds can be found. The last thing our country needs is <u>further</u> barriers to innovation and the formation of new high-tech businesses.

The CHAIRMAN. Thank you very much. That is a great statement, Mr. Bunnell.

Mr. Blansett.

STATEMENT OF LARRY BLANSETT, PRESIDENT, BLANSETT PHARMACEUTICAL, INC., ON BEHALF OF ALLIED PHARMACEUTICAL GROUP, APG

Mr. BLANSETT. Mr. Chairman, thank you for allowing me to appear before you today. My name is Larry Blansett. I am the president of Blansett Pharmacal Company located in North Little Rock, AR. My company is a small brand name distributor of prescription pharmaceutical products.

I have been in the pharmaceutical industry for 23 years, and I have co-founded two other pharmaceutical companies prior to Blansett. Both previous companies became national in size, and it so happens both were in Louisiana, one of which was purchased by Boots of Great Britain when they entered the U.S. market. They developed ibuprofen that you hear so much about today.

Today I represent Allied Pharmaceutical Group, APG, consisting of 20 small brand name manufacturer/distributors that are similar to mine. I am also a member of the National Pharmaceutical Alliance based in Washington, NPA, which has 150 member companies. I understand NPA has submitted a written response to the user fee proposal.

First, allow me to distinguish between generic firms and small brand name firms. I think this is a very confusing issue that needs to be addressed.

Major companies face competition from two primary sources:

1. Generic houses' or generic companies' whose interest is primarily in top selling brand name prescription drugs that have come off patent. Generally they are not interested in products with sales less than $50 million, sometimes $25 million.

2. Small brand name companies such as mine compete head on with major companies in offices of physicians all over the country. We compete head on with the majors on their turf with detail representatives detailing products that are similar to theirs, oftentimes have advantages, but some of these products have been on the market for as long as 25 years.

Generally these products by the majors may make up a total market per product of $1 million to $25 million. Our companies that I represent as well as mine generally sell our prescription products to the drug stores or wholesale drug companies at up to 50 to 60 percent less than the major brand name products. Since we put our brand name on the product, however, we have to have strict compliance on quality and control just as the majors, whereas as you know there is some question as to the generic products.

Many times these small companies that I am talking about grow and become major companies. They have in the past, some of which I have been involved in.

Allied Pharmaceutical Group is highly opposed to the user fee proposal, just as every small company is that I am aware of, along with consumer groups such as AARP and others have been in the past. User fees must not come to pass for the following reasons:

1, they are anticompetitive, giving an unfair advantage to major firms.

2, they are inflationary, raising the cost of health care products, specifically prescription drugs for Medicaid recipients and the disadvantaged.

3, they discriminate against smaller companies, and

4, they would further complicate the drug review process by building in an automatic method for raising income by the agency.

In other words, new drug applications (NDAs), the cost would be or could be assessed, whichever the case may be, to raise larger sums as opposed to allowing a firm to file an abbreviated new drug application known as an ANDA.

It is at the Food and Drug Administration's discretion in every instance whether a drug is considered an unapproved new drug or a new drug or it is simply a version of an older product requiring an abbreviated new drug application.

On the first point, the small brand name companies cannot afford the $300,000 fee for an NDA and $20,000 for an ANDA. I am talking about companies whose total earnings in a year range from $200,000 to $15 million in sales, companies who employ anywhere from two employees to 50 employees, not 500. Yet in the past, these companies have been able to grow by taking over formulas that have been proven to be safe and effective and making slight revisions that would improve the effectiveness of that product and mark them at up to half the price and grow and become national companies.

The approval of the drug application should be the only price a company must pay for the privilege of selling their product, not an additional tax in the form of user fees. Major pharmaceutical companies somewhat silently endorse the idea because they know small competitors would be eliminated. I know you are aware that Senator Pryor and others are encouraging competition while they are investigating drug pricing.

In regard to the second point raised, the cost of getting a drug product on the market using a proven combination not currently on the market would be increased by several dollars per prescription. The cost of prescription drugs will go up, especially under Medicare, for proven combinations.

Third, the user fee could more appropriately be called the privilege tax, creating a club consisting only of elite companies who can pay the price and are allowed to join.

Finally, should the FDA need to raise additional funds, they could determine during the review process that a simple drug product would require an NDA instead of an ANDA and charge user fees accordingly.

Currently, a drug product is considered a new drug by simply changing the color of the logo from the existing major brand product. If user fees are implemented, the FDA would have the choice to charge $300,000 or $20,000 merely for changing the color of the logo.

The CHAIRMAN. Larry, excuse me just a minute. I have only 5 minutes to get to the Floor for a rollcall vote. If you will hold right at that point, we will complete your testimony as quickly as I can get back. If all of you gentlemen will just stand at ease for a

minute until we can make this rollcall vote, we will be back and get into questions.

We will stand in recess for about 15 minutes.

[A brief recess was taken.]

The CHAIRMAN. Larry, according to my notes we are down to page 4. If you would start at that point, the top paragraph.

Mr. BLANSETT. Finally, should the FDA need to raise additional funds, they could determine during the review process that a simple drug product would require an NDA instead of an ANDA and charge user fees accordingly.

Currently a drug product is considered a new drug by simply changing the color of the logo from the existing major brand product. If user fees are implemented, the FDA would have the choice to charge $300,000 to $10,000, which should be, I understand, $20,000 for an ANDA——

The CHAIRMAN. In my copy of your testimony you have, "If user fees are implemented, FDA would have the choice to charge $300,000 as opposed to $100,000'.

Mr. BLANSETT. That should have been changed to $20,000 for an ANDA.

The CHAIRMAN. OK, go ahead.

Mr. BLANSETT. The cost of the NDA is $300,000, and the proposed cost of an ANDA is supposedly $20,000—that was a typo that just was not caught—merely for changing the color of a logo.

The enforcement activity of the agency needs to be evenhanded and fair. Considerable money is wasted by the FDA trying to regulate and remove products from the market that have a long history of safety and effectiveness, and it is done in an arbitrary and unfair manner.

One of many examples is my drug product, Anolor DH, an analgesic for pain. The major brand product, Fiorinal with codeine, had been marketed safely for 23 years when the FDA decided it was a new drug. Court activity began, causing 20 or more small brand name companies to lose their products, including my company, because none of us could afford to defend the product in court.

After 4 years of ligation, only two of these products remain on the market, the major brand product previously mentioned and one other, Esgic with codeine. To my knowledge, Esgic with codeine has never been regulated in spite of numerous letters from Congressmen in several states inquiring how the company is able to continue marketing its products.

I might add that I understand that they are in court now, but it only happened after about 2 years of letters from various Congressmen from several states. So it was not something that was evenhanded.

A pharmacist can purchase Esgic with codeine in Little Rock, AR, Atlanta, GA, and anywhere else in the country today, and my product and many others have been taken out of the marketplace.

Additionally, Esgic did not enter the market until 1986, 2 years after the FDA began regulating those products as unapproved new drugs.

Going back to the major brand Fiorinol product, when the court activity began on this product in 1984 it sold for $23 per 100 average wholesale price, AWP. Today the AWP is $65, an increase of

almost 300 percent. So this is an example of what happens when major companies are able to defend, right or wrong, whether the FDA is right or wrong in court, while the other ones go by the wayside, and the products that are safe and effective that have been on the market for a number of years we feel is totally uncalled for as long as it is totally safe.

The only beneficiaries to the enactment of user fees would be the FDA and major pharmaceutical houses. While we all admit that the FDA needs money, the funds to support the agency should not be provided at the expense of small manufacturers in the public.

[The prepared statement of Mr. Blansett follows:]

STATEMENT OF LARRY BLANSETT, PRESIDENT
BLANSETT PHARMACAL, INC.
BEFORE THE
SENATE COMMITTEE ON SMALL BUSINESS
JUNE 13, 1989

Mr. Chairman, thank you for allowing me to appear before you today. My name is Larry Blansett. I am president of Blansett Pharmacal, Inc., located in North Little Rock, Arkansas. My company is a small brand name distributor of prescription pharmaceutical products.

I have been in the pharmaceutical industry for 23 years and co-founded two other small companies prior to Blansett Pharmacal. Both earlier companies became national in size; one was purchased by Boots of Great Britain when they entered the U.S. market.

Today, I represent Allied Pharmaceutical Group (APG) which consists of 20 small brand name manufacturer/distributors similar to my company. I am also a member of the National Pharmaceutical Alliance (NPA) which has 150 member companies. I understand NPA has submitted a written response to the user fee proposal.

First, allow me to distinguish between "generic" firms and "small brand name" firms. Major companies face competition from two primary sources:

(1) "generic" houses whose interest is in brand products with sales in excess of $50,000,000 and for which the patent has expired; and

(2) "small brand name" companies that compete head-on with the majors on older combination drug products with sales from $1,000,000 to $25,000,000 (usually at 50-60% loss in cost). Often their products offer advantages and they become major in size.

Allied Pharmaceutical Group is highly opposed to the user fee proposal, just like every small company and consumer group, such as AARP and others.

User fees must not come to pass for the following reasons:

(1) they are anti-competitive, giving an unfair advantage to major firms;

(2) they are inflationary, increasing the cost of health care products - specifically prescription drugs for medicaid recipients and the disadvantaged;

(3) they discriminate against smaller companies; and

(4) they would further complicate the drug review process by building in an automatic method for raising income

by the agency, e.g., New Drug Application (NDA) costs may be assessed to raise larger sums instead of allowing a firm to file an Abbreviated New Drug Application (ANDA).

On the first point, small brand name companies cannot afford the $300,000 fee for an NDA and $20,000 for an ANDA. The approval of a drug application should be the only price a company must pay for the privilege of selling a product, not an additional tax in the form of user fees. Major pharmaceutical companies somewhat silently endorse the idea because they know small competitors would be eliminated because of the costs involved.

In regard to the second point raised, the cost of getting a drug product on the market using a proven combination not currently on the market would be increased by several dollars per prescription. The cost of prescription drugs will go up, especially under medicare, for proven combinations.

Third, the "user fee" could more appropriately be called the "privilege tax," creating a club consisting only of elite companies who can pay the price and are thus allowed to join.

Finally, should the FDA need to raise additional funds it may determine during the review process that a simple drug product requires an NDA instead of an ANDA, and charge user fees

accordingly. Currently, a drug product is considered a "new drug" by simply changing the color of the logo from the existing major brand product. If user fees are implemented the FDA would have the choice to charge $300,000 as opposed to $100,000, merely for changing the color of the logo.

The enforcement activity of the Agency needs to be even-handed and fair. Considerable amounts of time and money are wasted by FDA trying to regulate and remove products from the market that have a long history of safety and effectiveness (in some cases 25 years or longer) in the view of both physicians and patients, and it is done in an arbitrary and capricious manner. Unless there have been at least two well controlled clinical studies by medical experts published in nationally recognized scientific journals, these older products can be determined to be "unapproved new drugs" requiring either a NDA or ANDA by using this "technicality" in the drug approval process.

When applied to drugs with a long history of safety, this is a waste of taxpayer money and forces practically all small companies from the market place. The expense of complying with this requirement (when used) can easily run as high as several hundred thousand dollars. Small companies are usually not in the position of defending themselves effectively against enforcement activity, or to hire expensive consultants, and, invariably, major companies monopolize the market.

One of the many examples of FDA's effectively shutting small companies out of the market place is my drug product Analor DH; several other smaller firms also had similar products. Here is a case in point where the major brand product, Fiorinal with Codeine had been marketed for twenty-one years. The Agency did not require either a NDA or ANDA for the drug until 1984. Then, since there were supposedly no "published studies" on the major brand or smaller company products they were declared "unapproved new drugs." The FDA has been in court with the major company for five years trying to remove their product from the market as through it were a dangerous new drug.

Immeasurable amounts of time and money have been spent because of FDA's effort to remove a drug that is generally recognized as safe and effective. The cost for the major brand product has increased from $23.00 to $65.00 per 100 (average wholesale price - AWP), an increase of 283%. All other products have been regulated off the market, with the exception, for some unexplained reason, of the product Esgic with Codeine manufactured by Forest Labs. This product did not enter the market place until 1986, two years after regulatory activity made it illegal, and FDA did not take regulatory action against it until 1988.

For these reasons and others, numerous medical experts believe the FDA is not fair and even-handed in its regulatory actions, and wastes considerable time and money on matters that

are trivial. FDA's resources should be used regulating and evaluating "new entity" drug products and existing drug products with known problems such as toxicity, not on a witch-hunt of proven products.

How this applies to the "user fee" proposed by the Agency is to highlight the inconsistent enforcement and evaluation policies it pursues. By its own discretion FDA can either take no action on certain products that are either similar or the same, or require a NDA or ANDA. The fees would be assessed accordingly and would be as arbitrary and capricious as their other actions.

The only beneficiaries to the enactment of user fees would be the FDA and major pharmaceutical houses. While we all admit that the FDA needs money, the funds to support the Agency should not be provided at the expense of small manufacturers and the public.

The CHAIRMAN. Thank you very much, Mr. Blansett.
Mr. Holveck.

STATEMENT OF DAVID HOLVECK, PRESIDENT, INVITRO DIAGNOSTICS, CENTOCOR, MALVERN, PA

Mr. HOLVECK. Mr. Chairman and Members of the subcommittee, my name is David Holveck. It is my pleasure to appear before you today on behalf of Centocor, Inc., an independent biotechnology company founded in 1979. Centocor is headquartered in Malvern, PA, where it employs 325 people.

I am here today to speak for small business communities' interest in the proposed legislation that would require user fees to be levied for FDA approvals for certain products under the agency's jurisdiction.

At the onset, I must state that Centocor is against this fee. Centocor is a leading manufacturer in a branch of biotechnology concerned with monoclonal antibodies. The company employs these extremely specific immune compounds to develop diagnostic and therapeutic products for the human health care. Our diagnostic blood test products designed to aid in the detection and management of cancer are marketed worldwide. One of these products, a test for the management of ovarian cancer, was approved by the FDA in 1987.

Centocor is also developing injectable imaging agents for diagnostic procedures. When used in conjunction with conventional imaging equipment, these compounds allow physicians to determine the location and extent of cardiovascular disease within the body.

In the therapeutic area, Centocor is clinically testing drugs to treat and prevent blood clot related disorders and deadly hospital infection.

As a small company, Centocor represents a critical element in the early commercial development of this new technology. By serving this function, Centocor and other small companies are essential to the competitive survival in the United States. To burden such small companies which are by definition cash poor with fees required for marketing entry would dramatically impact the technological leadership and the competitive strength of the country.

As a pharmaceutical company Centocor is particularly vulnerable to such added cost burdens as user fees. The pharmaceutical industry has extremely high barriers to entry. These barriers include the high cost of research, clinical affairs, large scale manufacturing, and marketing.

A diagnostic product will typically cost from $10 to $25 million to develop and introduce. A pharmaceutical product can cost in the range of $80 to $100 million. A significant percentage of these development funds is already devoted to managing the regulatory and approval process. Any additional cost burden would dramatically affect the ability of small innovative companies to make the transition to fully operational and profitable pharmaceutical concerns.

I would also like to discuss our concern about the issue of trade balance and trade issues between this country and others that participate in the world market. Clearly, the health care industry is

worldwide in scope. U.S. companies depend heavily on revenues from foreign markets just as foreign companies depend heavily on our markets.

Pharmaceutical companies of all sizes must compete worldwide to recoup the tremendous up-front investment required to develop drugs and medical devices. A user fee in the United States could be misread as a way of restricting participation or adding cost of participation in the U.S. market.

Adoption of such a fee could cause individual countries in the worldwide markets to reciprocate. As a result, the cost burden of user fees would not just be limited to the United States but would include international markets as well.

We feel strongly that the FDA plays a constructive and critical role in development of safe and effective products for human health care. We are strong advocates of increasing the resources available to this important Government agency; yet, we believe it should remain a pure Government agency, not an industry-funded regulatory body.

The FDA was established to ensure the safe and reliable products that reach the American public. The agency should continue to serve the people effectively without industry support.

In summary, we feel that small business plays an integral part in the development of innovative ideas and in catalyzing the transition from research breakthroughs to commercial products. Small companies are therefore critical to the competitive and economic health of the United States. Any element that adds to the already substantial financial and technical hurdles faced by small health care companies would restrict innovation, diminish competition and hinder the access of citizens throughout the world to the benefits derived from important advances in medical technology.

We strongly recommend that the user fee legislation be rejected and that more traditional forms of financing be developed to support the just and valuable efforts of the Food and Drug Administration.

Thank you for your time, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Holveck.

Mr. Holveck, is your company publicly held?

Mr. HOLVECK. Yes, it is, Mr. Chairman.

The CHAIRMAN. Is that the sum total of the company, 325 employees in Malvern?

Mr. HOLVECK. That is correct. There is a small manufacturing plant in Lydon, The Netherlands, of which they are a part of that 325.

The CHAIRMAN. The reason I was asking, I did not want to ask you for proprietary information, but if it is publicly held that would be public information.

What were your sales last year?

Mr. HOLVECK. Our product sales were $27 million. Out of that $27 million, approximately 75 to 80 percent was from the international markets.

The CHAIRMAN. Is this an ovarian cancer test?

Mr. HOLVECK. Yes, it is, Mr. Chairman. It is an invitro diagnostic test. By that, we analyze the blood from the patient.

The CHAIRMAN. How does that differ from a PAP smear?

Mr. HOLVECK. A PAP smear is analyzing the cells from the uterine wall.

The CHAIRMAN. It does not detect ovarian cancer?

Mr. HOLVECK. That is uterine cancer. In this case we are talking about the ovaries.

The CHAIRMAN. If the ovary was cancerous, it would not emit any cancer cells that would be picked up by a PAP smear?

Mr. HOLVECK. Not normally, no. It is usually organ specific, so the PAP smear is a result of going in and scraping the wall of the uterus.

In this test we are taking a blood sample and picking up the substance in the blood.

The CHAIRMAN. What other diagnostic tools do you manufacture?

Mr. HOLVECK. We have currently a diagnostic test for the management of pancreatic cancer. We have a test for the management of breast cancer. These currently are going through their approval cycle. They are marketed in the European and Japanese community, however, at this point.

The CHAIRMAN. They are not allowed in this country yet?

Mr. HOLVECK. That is correct.

The CHAIRMAN. If you are licensed, then, of course you will have an exclusive in this country; is that right?

Mr. HOLVECK. We will be able to market in this country. That does not preclude another company from submitting a PMA for the approval of a breast cancer test or a pancreatic monitoring test.

The CHAIRMAN. But it could not infringe on the same thing—what shall I say, contents?

Mr. HOLVECK. That is correct. The antibody that we would use in our product is unique to our product. They could develop a different antibody and market a test for the same clinical purpose using a different antibody.

The CHAIRMAN. How many employees did your company have before this ovarian cancer test was approved?

Mr. HOLVECK. Approximately 175.

The CHAIRMAN. What was the principal function of the company then?

Mr. HOLVECK. Primarily diagnostics at that point. It was the growth of the company to the 325 mark that was primarily a result of our decision to move into the pharmaceutical side or therapeutic side. Through that decision we had to add what they call CRAs or Clinical Research Associates to work in the hospitals to do clinical trials, statisticians as well as regulatory people to supervise and medical science people to write protocols.

The CHAIRMAN. Were you profitable last year?

Mr. HOLVECK. Yes, we were profitable last year.

The CHAIRMAN. What do you think it cost you totally, for example, to get the FDA approval on those ovarian cancer tests?

Mr. HOLVECK. We did go through the estimate and came up with approximately $2 to $3 million. That embodied all of the clinicals, the time spent analyzing the data, the time and money spent with the institutions who did perform the clinicals, and then certainly the time spent working with the FDA. It was a process that took approximately 3 years for approval.

The CHAIRMAN. Mr. Blansett, if I understand it you were marketing an analgesic.

Mr. BLANSETT. Yes, sir.

The CHAIRMAN. You and several other companies in the United States were making a similar product; is that correct?

Mr. BLANSETT. Yes, sir.

The CHAIRMAN. You named this other product, and I guess FDA thought it was the same thing, Fiorinol.

Mr. BLANSETT. Yes, sir.

The CHAIRMAN. Is that the name of the product?

Mr. BLANSETT. Fiorinol with codeine, yes, sir.

The CHAIRMAN. Is that a pain——

Mr. BLANSETT. That is a pain product. It is marketed by a major company.

The CHAIRMAN. Whose major company?

Mr. BLANSETT. Sandoz Pharmaceuticals. The product had been on the market for 23 years at the time that it was declared a new drug.

The CHAIRMAN. Their product was?

Mr. BLANSETT. Yes.

The CHAIRMAN. How long had you been marketing yours?

Mr. BLANSETT. At that time I had been marketing mine for about 2 years in 1984.

The CHAIRMAN. Let me just ask you. It is my guess this is really a legal question. Would you have had the right to manufacture the same product after a certain number of years had their patent run out on their product?

Mr. BLANSETT. Well, yes, sir. You see, Senator Bumpers, the drugs that had been on the market for a number of years went through progressive stages of desi-review, if you will. At one time, primarily the safety of the product was important, and then effectiveness came into being. Along the way they looked for the effectiveness part of it.

Some products that had been on the market for a number of years were reviewed if there had been reported instances of problems. Otherwise, they were grandfathered in and were not required to have a new drug application. This was the case with the major brand product. They grandfathered the product in because it had been out there for so many years and they never had bothered it. It was known to be safe, never any reported instances of problems with toxicity.

The CHAIRMAN. I am curious about what they did that caused FDA to treat it as a new product.

Mr. BLANSETT. I think, Senator, post-etherol, you know, back a number of years ago there was sulfanilamide which caused problems. Then you have the thalidomide situation that occurred. Then along the way Mer-29 which never really reached the marketplace. Then you had E-ferol in 1983. These were unfortunate instances that occurred along the way that each time these things would happen and people were hurt or damaged from this, the FDA would start reviewing old drugs that had been on the market for a number of years in the light of toxicity or whatever, and they overreacted in many cases to protect themselves, I think, by requiring applications on certain products.

Unfortunately, they have gone so far they have gone back on products like Fiorinol 3 that never had been a problem but they decided after the post-E-ferol incident, which was totally uncalled for and should have never happened, they would go back and treat it as a new drug, thus requiring that it have a new drug application.

A simple Abbreviated New Drug (AND) application, would not suffice, so they required the major company along with the rest of us to either defend ourselves in court or the product would be pulled. I along with 10 companies, smaller brand name companies, formed a group that consisted of some consultants who were ex-FDAers who worked with the agency, and we were able to continue through an agreement supposed reached to keep our product on the market.

The major company as at that time, however, having to defend themselves in court.

The CHAIRMAN. Against FDA?

Mr. BLANSETT. Yes. Their position was it was not a new drug. By the FDA's own terminology it was not a new drug, but if they said it was a new drug then you had to defend it in court, and that is what they have done.

The CHAIRMAN. Had your product been licensed by FDA, approved by FDA?

Mr. BLANSETT. Well, the way you enter on products of that type that have been on the market for a number of years, you simply file a product listing with the FDA to make them aware of your product and the ingredients that it has. Now this is prior to 1984. That is what we did. There were no drug applications required at that time on a product that was similar to an existing product.

The thing that happened out of this was that once we formed our group to do research, there was some push and pull that took place within our group, and we were forced out along with nine other companies.

I took my research to Arkansas where it was continued the same way that it was being done. Everyone that left that group lost their product except the three companies that stayed with those consultants who were ex-FDA officials.

I am getting into another area more than what you asked for, but I think it is public knowledge.

The CHAIRMAN That is a little bit aside from user fees, but I was just curious if you had in fact gotten that approval of yours and what it had cost you to do it.

Mr. BLANSETT. We are filing one now. We are getting ready to file an Investigational New Drug (IND) application, and we do not know what the cost is going to be because as a small company like ourselves, we have never filed one before. Obviously if this user fee came into effect, we are talking about a lot of money, and once we file the cost of the NDA is going to be quite expensive.

The CHAIRMAN. What do you call this application that you are getting ready to file?

Mr. BLANSETT. An IND.

The CHAIRMAN. I do not have that in my tentative fee list, so I do not know what they are planning to charge for that.

Mr. BLANSETT. It is an Investigational New Drug application, which in this case we have to file a protocol as to how we intend to conduct the study and what we intend to do about staying in compliance with what Food and Drug requires. I am not certain when the user charge begins on an Investigational New Drug application, if it is at the time you file or when you file for the NDA.

The CHAIRMAN. Mr. Holveck, let me come back to you for just a moment. If you were forced to put up $100,000 or $300,000 or whatever, as a matter of company policy would you try to pass that on, or would you eat it, or would you just do what came naturally, whatever you thought you could do? If you thought you could pass it on, you probably would? Is that a fair statement?

Mr. HOLVECK. I think a fair statement would be that we would look at the program from a financial perspective on a return on the investment, and I think that your ability to pass on is not a correct statement, if you would, we would look at.

We would look at relative to the cost of the program, the return on that investment; and clearly, whatever we could charge is going to be pretty heavily set by HCFA and reimbursement.

I think one of the issues that at least is alluded to was that FDA approval guarantees a financial return. An FDA approval is on the road of an approval process but is decoupled from reimbursement. That is a separate set of filings.

So I think the process which you talked about relative to user fees would be looked at relative to the program's overall cost. Only then, only after you have passed the approval process then would you certainly apply for reimbursement. There is quite a separation there.

I think it is wrong the way it has been presented that there is a direct relationship between approval and financial return. There is not.

The CHAIRMAN. Based on what you just told me you spent a couple of million dollars, that is on paperwork and the long ordeal of testing everything else, I guess.

Mr. HOLVECK. That is right. All of that is entailed in order to meet a safe and efficacious filing. It is an expensive process. I think the fee is again a part of how you analyze the return on that investment, and I think anything that further burdens that is a problem to deal with.

The CHAIRMAN. Mr. Bunnell, do you have any competition in this ventilator business?

Dr. BUNNELL. Yes. We have two domestic companies that are actively producing a device similar to ours and also a Japanese and a Swiss company.

The CHAIRMAN. How many of those devices does a 500 bed hospital need?

Dr. BUNNELL. All the hospitals that take care of babies would use these, and the most we have sold to any hospital is five units to the Childrens Hospital in Philadelphia.

The CHAIRMAN. They are $23,000 each?

Dr. BUNNELL. Yes.

The CHAIRMAN. When was that device approved?

Dr. BUNNELL. Just about 1 year ago.

The CHAIRMAN. How long had you worked on it?

Dr. BUNNELL. Sixteen years.

The CHAIRMAN. Sixteen years?

Dr. BUNNELL. Yes.

The CHAIRMAN. Does your company do anything else now except manufacture that?

Dr. BUNNELL. That is our major product. We have one other smaller product that we spun off in earlier days, a little monitor. It is kind of a "me-too" product.

The CHAIRMAN. I guess the benefits of your device have been conclusively shown.

Dr. BUNNELL. It is still quite controversial from a couple of standpoints because it is so different than what people are used to using. It is what I call a missionary sale. I have to go out and lecture and teach and get people to buy into the concept. Then we also have the obstacle of the competition that is coming along, and people are in doubt as to whether our approach to this technology is superior to the other approach that is supposedly around the corner. So there is always that hesitation.

The CHAIRMAN. How do their sales of that device run compared to yours?

Dr. BUNNELL. We are the only company that has FDA approval.

The CHAIRMAN. Are you?

Dr. BUNNELL. Yes. So I am certain we are doing better than anyone else, but I have been surprised at how well they do.

The CHAIRMAN. They cannot sell that product without FDA approval, can they?

Dr. BUNNELL. Yes, you can sell them as investigational devices, and if the product is produced outside of the United States you can sell it to foreign countries.

The CHAIRMAN. Do you have any foreign market, incidentally?

Dr. BUNNELL. We are just trying to open up Canada right now. It is very expensive to export, so we have very limited funds to do that right now.

The CHAIRMAN. Your company is not profitable yet, I take it?

Dr. BUNNELL. I think for 1988 on sales of about——

The CHAIRMAN. Do you have anything to cure colds, incidentally?

Dr. BUNNELL. Not yet.

Our sales in 1988 were around $900,000, and I think we made a profit of maybe $12.

The CHAIRMAN. You are hoping it will be profitable this year then?

Dr. BUNNELL. It is not audited yet, but we are very close.

The CHAIRMAN. If you were in the process today, would a $300,000 user fee on that be a problem for you?

Dr. BUNNELL. Yes, I guess you could say that. I have seen $90,000 proposed for the type of approval that we would need.

The CHAIRMAN. I did not know that; $90,000?

Dr. BUNNELL. Right now, $90,000 represents 1 month's cost for our company, and back in the days when we were actively pursuing this approval it represented up to 3 or 4 months operating capital. So it is a very significant fee, very significant.

The CHAIRMAN. Well, gentlemen, I thank all of you very much for being here today. All of your testimony has been very helpful to

us, and we appreciate the time you took to prepare it and the time you took to come here and be with us today.

Thank you again.

Our third panel today is Mr. George K. Meszaros, president and general manager of Polychem, Inc., Kensington, MD, representing the Contact Lens Manufacturing Association; and Ralph Green, D.D.S., executive vice president, Collagen and Biomedical, Palo Alto, CA, representing Dental Implant Manufacturers Association.

Mr. Meszaros, since your name is first, please proceed.

STATEMENT OF GEORGE K. MESZAROS, PRESIDENT, POLYCHEM, INC., KENSINGTON, MD

Mr. MESZAROS. Mr. Chairman, my name is George K. Meszaros. I am president of Polychem, Inc. We are members of the Contact Lens Manufacturers Association, CLMA for short. I am past president of the Contact Lens Manufacturers Association and have been part of the contact lens industry for 35 years. The current president, Mr. Carl Moore, could not come to Washington to appear before you today, and I am honored to take his place.

On behalf of the 150 member companies of CLMA and their employees, I thank you for calling this hearing and allowing us to testify.

Typical of the medical device industry as a whole, the members of our association are mostly small businessmen. Regulatory costs of any kind have a disproportionately large impact on small businessmen. They affect us much more than they affect our larger competitors.

The imposition of so-called user fees would only worsen the problems already faced by small manufacturers of medical devices, especially contact lens manufacturers. Some years ago the Congressional Office of Technology Assessment, (OTA), studied the impact of the medical device amendments on the industry. The OTA concluded, "Major portions of the medical device amendments have not been implemented by FDA, and some may not be workable. As implemented so far, the regulatory process has posed the greatest problem for small manufacturers of contact lenses." This was in October 1984.

Mr. Chairman, the problems have not gone away since that OTA report was written. User fees would only make matters worse for small business; therefore, the Contact Lens Manufacturers Association is opposed to FDA user fees for new product approvals.

To assess the impact of the proposed user fees on the contact lens industry, I must briefly review the situation in which we find ourselves today. The now commonplace rigid gas permeable, or RGP, daily wear contact lens is the mainstay of the small manufacturing laboratories in this country. With it, we can compete with the larger conglomerates who dominate the soft contact lens market.

Illogically, the daily wear RGP lens is regulated as a "class III device", the most restrictive and most expensive level available under the law. The United States to my knowledge is the only Nation in the world which regulates rigid lenses at anything like this restrictive level.

Equally unique is the manner in which we must do business. Unlike, for example, the dental laboratory, the contact lens laboratory is not able to simply purchase materials from a supplier and make the devices. In our case the materials are small plastic disks called "buttons" from which lenses are made.

Instead, we must first approach a button manufacturer. It is he who holds the so-called PMA or premarket approval issued by the FDA. The button manufacturer must then agree to file a PMA supplement with FDA to add the laboratory as an "alternate manufacturing site" to the button manufacturer's own PMA.

As a practical matter, it is already all but impossible for a small businessman to enter the market as a manufacturer of contact lenses. To do so, he or she would first have to buy or lease the needed space; purchase and install all the needed equipment; and retain qualified technical staff. After all this, however, there is still no assurance that the new company will even be able to purchase the RGP lens blanks needed in order to compete. Yet all this investment would have to be committed to first.

The new company would then have to approach one of the RGP button manufacturers to ask that it be placed on the company's PMA. If the button manufacturer is agreeable, a PMA supplement must be prepared and submitted to FDA. A minimum 30-day wait for approval then ensues, after which, if all goes well, the new laboratory could start purchasing lens buttons and commence operations.

If the button manufacturer changed the polymer in some way, a new PMA or supplement may be required, and the independent laboratory may have to be reconfirmed as an alternate manufacturing site for this modified material.

If, in addition to all this, the FDA charges a fee for reviewing the PMA supplement, it seems inevitable that the cost will be passed on to the laboratory. This would have an immediate and adverse impact on laboratories seeking to obtain RGP lens blanks. Aside from imposing a new barrier to entering this industry for the first time, it would impact existing laboratories when they sought to obtain newer RGP polymers. In that case, a new supplement would have to be filed.

Theoretically, small laboratories can obtain their own PMAs. One way is to get permission from a button manufacturer to incorporate by reference certain portions of the button manufacturer's PMA, but the average small manufacturing laboratory is simply not in a position to pay anything like the $90,000 that is being spoken of as the PMA fee for reviewing a PMA.

It is not surprising that the entry of small businessmen into this market has all but ceased. Instead, we have seen years of continued consolidation in the contact lens field as a result of the merger and acquisition activities of large conglomerates. Small contact lens companies have been disappearing for years as a result of this process.

Mr. Chairman, the real problem with user fees is that they would encourage and perpetuate needless and anticompetitive regulations. Those regulations which are actually needed to protect the public should and must be supported by public funds. Where these regulations are obsolete, anticompetitive and serve only lim-

ited commercial interests of a few large corporations, public funding is not justified and should be terminated along with the regulations themselves.

This requires constant review by the FDA itself and constant oversight by Congress such as your distinguished committee is providing today, Mr. Chairman.

Setting up the present review process as a self-sustaining activity generating fees that account for a significant portion of the FDA's total budget is a bad idea. It will result, among other things, in the contact lens market becoming the sole domain of a handful of large corporations having the resources needed to meet these increased regulatory costs.

We fully recognize the vital importance of the FDA's mission, and we realize that the FDA must often react with a massive effort to unanticipated threats to the public health; but rather than resort to user fees, some way is needed to stop the waste of money the FDA already has.

Mr. Chairman, you have introduced just such a bill, S. 1094, cosponsored by Senators Kennedy and Hatch. Enactment of that legislation will, we estimate, provide substantial savings to the agency, probably as much as 40 percent of the total $13 million which FDA would raise by charging user fees for medical device reviews.

In closing, Mr. Chairman, contact lens manufacturers and other small businessmen are not looking for a handout or a subsidy from the FDA. By the same token, we are opposed to providing a subsidy to the FDA for the continuation of unjustified and anticompetitive regulatory requirements.

Thank you for allowing me to testify.

[The prepared statement of Mr. Meszaros follows:]

STATEMENT OF GEORGE K. MESZAROS
CONTACT LENS MANUFACTURERS ASSOCIATION
BEFORE THE U.S. SENATE COMMITTEE ON SMALL BUSINESS
JUNE 13, 1989

Mr. Chairman, my name is George K. Meszaros. I am president of PolyChem Incorporated. We are members of the Contact Lens Manufacturers Association (CLMA). I am a past president of the CLMA and have been part of the contact lens industry for 35 years. The current president, Mr. Carl Moore, could not come to Washington to appear before you today and I am honored to take his place. On behalf of the 150 member companies of the CLMA and their employees, I thank you for calling this hearing and allowing us to testify.

Typical of the medical device industry as a whole, the members of our Association are mostly small businessmen. Regulatory costs of any kind have a disproportionately large impact on small businessmen. They affect us much more than they do affect our larger competitors.

Congress recognized this when it passed the Medical Device Amendments of 1976. Over the objections of the Department of HEW, as it was then called, Congress established the Division of Small Manufacturers Assistance within what is now the Center for Devices and Radiological Health. This office for small manufacturers assistance has been helpful, but its mandate and resources need to be strengthened. It should be made into a

true ombudsman for small business interests at FDA. That would be the subject for another hearing, however.

The imposition of so-called user fees would only exacerbate the problems already faced by small manufacturers of medical devices, especially contact lens manufacturers. Some years ago, the Congressional Office of Technology Assessment (OTA) studied the impact of the medical device amendments on the industry. The OTA concluded:

> "[M]ajor portions of the Medical Device Amendments have not been implemented by FDA and some may not be workable. As implemented so far,the regulatory process has posed the greatest problem for small manufacturers of contact lenses." (October 1984)

Mr. Chairman, the problems have not gone away since that OTA report was written. User fees would only make them worse for small business. Therefore, the CLMA is opposed to FDA user fees for new product approvals.

To assess the impact of the proposed user fees on the contact lens industry, I must briefly review the situation in which we find ourselves today. The now commonplace rigid gas permeable (RGP) daily wear contact lens is the mainstay of the small manufacturing laboratories in this country. With it, we can compete with the large conglomerates who dominate the soft

contact lens market. Illogically, the daily wear RGP lens is regulated as a class III device - the most restrictive and most expensive level available under the law. The United States, to my knowledge, is the only nation in the world which regulates rigid contact lenses at anything like this restrictive level.

Equally unique is the manner in which we must do business. Unlike, for example, the dental laboratory, the contact lens laboratory is not able to simply purchase materials from a supplier and make the devices. In our case the materials are small plastic disks called "buttons" from which the lenses are made.

Instead, we must first approach a button manufacturer. It is he who holds the so-called PMA (Pre-market Approval) issued by FDA. The button manufacturer must then agree to file a PMA supplement with FDA to add the laboratory as an "alternate manufacturing site" to the button manufacturer's own PMA.

As a practical matter, it is already all but impossible for a small businessman to enter the market as a manufacturer of contact lenses. To do so, he or she would first have to buy or lease the needed space, purchase and install all of the needed equipment, and retain qualified technical staff. After all this, however, there is still no assurance that the new company will even be able to purchase the RGP lens blanks needed in order to

compete. But all this investment would have to be committed first.

The new company would then have to approach one of the RGP button manufacturers to ask that it be placed on that company's PMA. If the button manufacturer is agreeable, a PMA supplement must be prepared and submitted to FDA. A minimum 30-day wait for approval then ensues, after which - if all goes well - the new laboratory could start purchasing lens buttons and commence operations. If the button manufacturer changed the polymer in some way, a new PMA or supplement may be required, and the independent laboratory may have to be re-confirmed as an alternate manufacturing site for this modified material.

If, in addition to all of this, the FDA charges a fee for reviewing the PMA supplement, it seems inevitable that the cost will be passed on to the laboratory. This would have an immediate and adverse impact on laboratories seeking to obtain RGP lens blanks. Aside from imposing a new barrier to entering this industry for the first time, it would impact existing laboratories when they sought to obtain newer RGP polymers. In that case, a new supplement would have to be filed.

Theoretically, small laboratories can obtain their own PMA's. One way is to get permission from a button manufacturer to incorporate by reference certain portions of the button manufacturer's PMA. But the average small manufacturing

laboratory is simply not in a position to pay anything like the $90,000 that is being spoken of as the PMA fee for reviewing a PMA.

It is not surprising that the entry of small businessmen into this market has all but ceased. Instead, we have seen years of continued consolidation in the contact lens field as a result of the merger and acquisition activities of large conglomerates. Small contact lens companies have been disappearing for years as a result of this process.

Mr. Chairman, the real problem with user fees is that they would encourage and perpetuate needless and anticompetitive regulation. Those FDA regulations which are actually needed to protect the public should and must be supported by public funds. Where these regulations are obsolete, anticompetitive, and serve only limited commercial interests of a few large corporations, public funding is not justified and should be terminated along with the regulations themselves. This requires constant review by the FDA itself and constant oversight by the Congress, such as your distinguished Committee is providing today Mr. Chairman. Setting up the present review process as a self sustaining activity, generating fees that account for a significant portion of the FDA's total budget is a bad idea. It will result, among other things, in the contact lens market becoming the sole domain of a handful of large corporations having the resources needed to meet these increased regulatory costs.

We fully recognize the vital importance of the FDA's mission. And we realize that the FDA must often react with a massive effort to unanticipated threats to the public health. But rather than resort to user fees, some way is needed to stop the waste of money the FDA already has. Mr. Chairman, you have introduced just such a bill, S. 1094 - cosponsored by Senators Kennedy and Hatch. Enactment of that legislation will, we estimate, provide substantial savings to the agency, probably as much as 40 percent of the total $13 million which FDA would raise by charging user fees for medical device reviews.

In closing, Mr. Chairman, contact lens manufacturers and other small businessmen are not looking for a handout or a subsidy from FDA. By the same token, we are opposed to providing a subsidy to FDA for the continuation of unjustified and anticompetitive regulatory requirements.

Thank you again for allowing us to testify.

The CHAIRMAN. Thank you, Mr. Meszaros.
Dr. Green.

STATEMENT OF DR. RALPH GREEN, EXECUTIVE VICE PRESIDENT, COLLAGEN BIOMEDICAL, PALO ALTO, CA, ON BEHALF OF THE DENTAL IMPLANT MANUFACTURERS ASSOCIATION

Dr. GREEN. Thank you, Mr. Chairman. My name is Ralph Green. I am executive vice president of Collagen Biomedical. I thank you for allowing me to appear here today.

I am speaking on behalf of the Dental Implant Manufacturers, Inc. It is a trade association representing the suppliers of the majority of dental implants. Most of our members are small companies, as is the case of many of the segments of the medical device industry.

The prime benefit of dental implant technology is to the partially or totally edentulous population. Typically, this is an elderly population, often on fixed and limited income.

Regulatory costs and policies which decrease competition and raise prices may limit the benefits of this technology to the affluent. Such policies and costs should be rejected unless there is a clear showing of need. We do not think that the case has been made for the FDA user fee's at this time.

As we understand the proposal, approximately $100 million would be raised by collecting fees from those undergoing agency review of new products and devices. Of this, $13 million would be collected from manufacturers of medical devices undergoing review. The rationale for such charges was stated by FDA Commissioner Young as follows:

> Our activities in these areas clearly benefit industry at the same time that they protect consumers, so we believe these charges are appropriate. If someone benefits from Government action, they should pay the Government. I believe that for all of the FDA product approval activities, there is a sound basis for expecting product sponsors to pay the Government's costs.

The real question is benefit to the industry and to the public. It cannot be simply assumed that such benefits exist for all of the FDA product approval activities. In fact, there is not the case, and some devices are subjected to over-regulation and needless review. This results in others receiving too little review and too little regulation.

We see no justification in simply adding a superstructure of the user fee to the present system. The FDA's product review process itself should be re-examined first. Otherwise, we may simply perpetuate a system that needs to be overhauled.

Among other things, the FDA request for user fee's should be considered seriously only after the agency has eliminated those reviews which are needless or whose cost is not offset by resulting benefits to the public. This has not yet happened, and such reviews are taking place. Furthermore, the kind of review that is needed is less likely to happen if a substantial portion of the agency's budget is derived from fees from product reviews conducted under the present policies.

In our industry, rather than having needless reviews eliminated, we have seen the reverse process taking place with respect to what is called the endosseous dental implant. These are small devices

now usually made of titanium or ceramic which are embedded into the upper or lower jaw for the attachment of artificial teeth. Their use dates back to antiquity.

Use of this type of device requires a skilled dental surgeon, but the device itself is not inherently dangerous. During the past 30 years, endosseous implants have been used extensively in this country and abroad. Since the passage of the Medical Device Amendment in 1976, they have been regulated under the premarket notification provisions of Section 510(k) of the Federal Food & Drug Cosmetic Act. No significant health or safety issues have emerged. There has been no indication that the present level of regulatory control is inadequate.

In the United States, it is estimated that over 1 million endosseous implants have been sold over the last 15 years with very few reported failures to date. Similar experiences are also noted in Europe and Japan. Thus, the risk of implants loosening or the loss of function appears to be relatively low.

Yet, the Food and Drug Administration has placed these devices on the fast track for implementing the regulation for submission of the premarket approval application. DIMA is proceeding as rapidly as possible to submit a reclassification petition to place these devices at a more realistic level of control where the PMA review will not be required.

The PMA requirement, as you know, applies only to devices placed in class III under the medical device law. That requirement, with or without user fees, should be imposed only on those devices which meet the definition of a class III device. The law defines those devices in part as follows:

1. Purported or represented to be for the use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.

2. Presents a potential unreasonable risk of illness or injury.

There is a mechanism to reassign devices out of class III if they do not meet the legal definition, reclassification. The importance of reclassification has been noted by an FDA official.

> Reclassification is important for two reasons. Without it, the center would ultimately drown in unnecessary regulatory minutia. Specifically, without reclassification we would, through the PMA process, continue to answer and re-answer the same scientific questions for which everyone already knows the answers.
>
> Clearly, the regulated industry would spend more money on product testing without resulting commensurate benefit to the public health. But there would be additional problems. Not only would an unavailable sum of resources be needed to expeditiously review the PMA's, but unnecessary PMA reviews would draw needed resources from the 510(k)s and IDEs. As a result, product marketing would stall.

We agree with those statements. We regret present indications that the FDA intends to subject the endosseous implant to just that kind of "unnecessary regulatory minutia." But, at least under the present system, the FDA has every reason to re-evaluate its priorities and not to waste scarce resources. Accordingly, we hope that our reclassification petition will receive careful consideration.

To sum up, in our industry we are faced with the prospect of an extraordinary new regulatory costs for a product type which has been safely marketed for decades. Until there is some better mechanism in place to ensure that needless product reviews are not going to be required, and that priorities will be established based

on risks that are real rather than conjectural, we cannot subscribe to the philosophy that all such product reviews are beneficial.

Accordingly, we cannot subscribe to the user fee concept as presently presented.

Thank you for the opportunity to present this review.

[The prepared statement of Dr. Green follows:]

TESTIMONY OF RALPH GREEN, PRESIDENT
DENTAL IMPLANT MANUFACTURERS ASSOCIATION
before the
SENATE COMMITTEE ON SMALL BUSINESS
June 13, 1989

Mr. Chairman, thank you for your allowing us to appear here today. The Dental Implant Manufacturers Association, Inc. (DIMA), is a trade association representing manufacturers of dental implants. Most of our members are smaller companies, as is the case with many other segments of the medical device industry.

The prime benefit of the dental implant technology is to the partially or totally edentulous population. Typically, this is an elderly population - often on fixed and limited incomes. Regulatory costs and policies which decrease competition and raise prices may limit the benefits of this technology to the affluent. Such policies and costs should be rejected unless there is a clear showing of need. We do not think that the case has been made for FDA user fees at this time.

As we understand the proposal, approximately $100 million would be raised by collecting fees from those undergoing agency reviews of new drugs and devices. Of this amount, $13 million would be collected from the manufacturers of medical devices undergoing review.

The rationale for such charges was stated by FDA Commissioner Young as follows:

> "Our activities in these areas clearly benefit industry at the same time that they protect consumers, and so we believe these charges are appropriate. . . . [I]f

someone benefits from government action, they should pay the government. I believe that for all of FDA product approval activities, there is a sound basis for expecting product sponsors to pay the governments's costs." (Testimony before Agriculture Subcommittee, Senate Appropriations Committee; April 4, 1989)

The real question is benefit, to the industry and to the public. It cannot simply be assumed that such benefit exists for all of FDA product approval activities. In fact, that is not the case. Some devices are subjected to overregulation and needless reviews. This results in others receiving too little review and too little regulation.

We see no justification in simply adding a superstructure of user fees to the present system. The FDA's product review process itself needs to be re-examined first. Otherwise, we may simply perpetuate a system that needs to be overhauled.

Among other things, FDA's request for user fees should be considered seriously only after the agency has eliminated those reviews which are either needless or whose cost is not offset by resulting benefit to the public. This has not happened yet, and such reviews are taking place. Furthermore, the kind of review that is needed is less likely to happen if a substantial portion of the agency's budget is derived from fees for product reviews conducted under the present policies.

In our own industry, rather than having needless reviews eliminated, we see the reverse process taking place with respect to what are called endosseous dental implants. These are small devices usually made of titanium or ceramic which are embedded

into the upper or lower jaw for the attachment artificial teeth. Their use dates back to antiquity. Use of this type of device requires a skilled dental surgeon, but the devices themselves are not inherently dangerous.

During the past 30 years, endosseous implants have been used extensively both in this country and abroad. Since the passage of the Medical Device Amendments of 1976, they have been regulated under the premarket notification provisions of Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act). No significant health or safety issues have emerged. There has been no indication that the present level of regulatory control is inadequate. In the United States, it is estimated that more than one million endosseous implants have been sold over the past 15 years with very few reported failures to date. Similar experience has been noted in Europe and Japan. Thus, the risk of implant loosening or other loss of function appears to be remarkably low.

Yet, the FDA has placed these devices on a fast track for implementing a requirement for submission of premarket approval applications (PMA's). DIMA is proceeding as rapidly as possible to submit a reclassification petition to place these devices at a more realistic level of control where the PMA review will not be required.

The PMA requirement, as you know, applies only to devices placed in class III under the medical device law. That requirement - with or without user fees - should be imposed only

on those devices which meet the definition of a class III device.

The law defines those devices, in part, as follows:

> (I) [P]urported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
>
> (II) presents a potential unreasonable risk of illness or injury (21 USC 360c(a)(1)(C)).

There is a mechanism to reassign devices out of class III if they do not meet the legal definition - reclassification. The importance of reclassification has been noted by an FDA official:

> "[R]eclassification is important for two reasons. . . . [W]ithout it, the Center would ultimately drown in unnecessary regulatory minutia. Specifically, without reclassification we would, through the PMA process, continue to answer, and re-answer the same scientific questions for which everyone already knows the answers. Clearly, the regulated industry would spend money on product testing without a resulting commensurate benefit to public health. But there would be additional problems. Not only would an unavailable sum of resources be needed to expeditiously review PMA's, but the unnecessary PMA reviews would draw needed resources from 510(k)s and IDEs. As a result, product marketing would stall.

We agree with those statements. We regret present indications that the FDA seems intent on subjecting endosseous dental implants to just that kind of "unnecessary regulatory minutia." But, at least under the present system, the FDA has every reason to re-examine its priorities so as not to waste scarce resources. Accordingly, we hope that our reclassification

petition will receive careful consideration.

To sum up, we in our industry, we are faced with the prospect of extraordinary new regulatory costs for a product type which has been safely marketed for decades. Until there is some better mechanism in place to insure that needless product reviews are not going to be required, and that priorities will be established based on risks that are real rather than conjectural, we cannot subscribe to a philosophy that all such product reviews are beneficial. Accordingly, we cannot subscribe to the user fee concept as presently presented.

Thank you for the opportunity to present these views.

The CHAIRMAN. Dr. Green, since I am in total agreement with you and Mr. Meszaros, there is no point in asking any questions, nor will any be submitted in writing. I thank you both very much for being here.

I have been deeply involved in the contact lens issue for a long time, unsuccessfully I might add, but in any event I appreciate both of you coming here today and presenting your testimony. You are both preaching to the saved, so we will not belabor this any further.

With that, we will stand adjourned. Thank you very much.

[Whereupon, at 4:38 p.m. the hearing was adjourned.]

APPENDIX

NATIONAL PHARMACEUTICAL ALLIANCE

SUITE 1200 • 1730 PENNSYLVANIA AVENUE, N.W. • WASHINGTON, D.C. 20006 • (202) 737-1634

June 12, 1989

The Honorable Dale Bumpers, Chairman
Committee on Small Business
428A Russell Senate Office Building
Washington, D.C. 20510

Re: The Issue of User Fees

Dear Senator Bumpers:

We are writing on behalf of the National Pharmaceutical Alliance (NPA) to present written testimony on The Issue of User Fees, which is the subject of a hearing by the Committee on Small Business scheduled for June 13, 1989.

NPA is an association of over 165 manufacturers and distributors of branded and non-branded generic pharmaceutical products for human and veterinary use. With few exceptions, most members are medium to small sized companies. The companies file, maintain, and supplement abbreviated new drug applications (ANDAs) and would be adversely affected by the imposition of user charges for these applications. More important, they believe that the public would be adversely affected by the imposition of user charges for pharmaceutical products.

I. Imposition of User Charges Will Increase the Cost of Drugs to Consumers

On September 24, 1984, President Reagan signed the Drug Price Competition and Patent Term Restoration Act of 1984. This was the most important pharmaceutical legislation since passage of the New Drug Amendments of 1962 that added to the 1938 Federal Food, Drug, and Cosmetic Act the requirement for premarket approval of new drugs for both safety and effectiveness. The 1984 legislation provides for the approval of generic versions of pioneer new drugs previously approved by the Agency without repeating costly tests to demonstrate safety and effectiveness.

As the title of the 1984 legislation suggests, a primary purpose of the legislation was to promote drug price competition that would result in decreased costs of drugs to consumers. At the bill signing ceremony, President Reagan specifically acknowledged this public purpose:

> The legislation will speed up the process of Federal approval of inexpensive generic versions of many brand name drugs [and] make the generic versions more widely available to consumers....
>
> Senior citizens require more medication than any other segment of our society.... They use about 25 percent...of all the drugs sold. With this bill, elderly Americans will have access to safe and effective drugs at the lowest possible cost. [I]t's estimated that consumers will save more than a billion dollars over the next 10 years....
>
> [T]he American people will benefit, because the Federal Government, the largest single consumer of drugs, will be able to purchase generic drugs at significantly lower costs. In 1983 alone, the Federal Government spent an estimated $2.4 billion for drugs through the medicaid program and in veterans and military hospitals.
>
> [T]his bill will provide regulatory relief, increased competition, economy in government, and best of all, the American people will save money, and yet receive the best medicine that pharmaceutical science can provide. (20 Weekly Comp. of Pres. Doc. 1359 (October 1, 1984))

Two years later a Commerce Department report indicated that the savings might be even greater than President Reagan had predicted because generic drug sales were increasing so rapidly.

User fees on FDA product reviews, including new drugs, antibiotic and certain supplemental applications, if implemented, would undermine the cost savings achieved by the 1984 legislation. Pharmaceutical companies, after all, cannot and will not absorb the costs of user fees; they will pass them on to the purchaser, and ultimately to the consumer, in higher drug prices. That means that the elderly, who use about 25 percent of all the drugs sold, will be hit the hardest. Under the current system, the cost of reviewing applications is shared by all taxpayers. Under a user fee system, that cost will be borne by purchasers and users of drug products.

Furthermore, because the Federal Government is the largest single consumer of drugs, it will continue to pay these added costs of user fees through Medicaid reimbursement and veterans and military hospital purchases. Thus, what appears at first glance to be a deficit-reducing panacea becomes upon examination, at

least for pharmaceutical products, a kind of shell game in which savings gained at the drug application stage are lost at the retail and reimbursement stage.[1/]

II. The Imposition of User Fees Would Place The Greatest Burden on the Generic Industry

Inconsistent procedures within the Center for Drug Evaluation and Research (CDER) will result in the generic industry bearing the greatest burden of user fees. Under CDER procedures, a full NDA may include different strengths for the product--all for a single user fee. A change in trade dress, such as a change in tablet color, may be obtained with a simple supplement to the NDA. Not so for drug approvals under ANDAs. FDA's Division of Generic Drugs (DGD) requires a separate ANDA for drug products that are in any respect different. Thus, different strengths, colors and dosage forms (e.g., tablets to capsules) of the same drug all require a separate application. Recently the Division has even begun requiring different applications for different manufacturing sites for the same drug product.

As a consequence of these inconsistent procedures, a disproportionately heavy burden will be placed on the generic industry from user fees. For example, the line of propranolol tablets comes in six different strengths--10 mg, 20 mg, 40 mg, 60 mg, 80 mg, and 90 mg. Whereas all strengths were approved in one NDA for the brand company, six applications must be submitted, one for each strength, for a generic company if it is to be able to offer the entire line of propranolol.

One might say, as FDA did when it proposed user charges to cover the costs of reviewing full and abbreviated new drug and

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1/ The 1984 legislation also provided up to five years of patent extension to compensate pioneer companies for patent time lost during FDA review of applications, thereby assuring them enough exclusive marketing time to recoup the costs of drug development. The Pharmaceutical Manufacturers Association announced last month that new drug research increased by more than a billion dollars in 1988 over 1987 and that the ratio of R&D to sales has increased by 40% since 1980. Thus, generic competition combined with patent extension has led to significant increases in new drug research. However, if user fees are imposed, brand companies could decrease drug research and development funding rather than pass the costs off to consumers. That would be as societally unfortunate as increasing the costs of drugs to consumers.

antibiotic applications and supplemental applications in 1985 (50 Fed. Reg. 31726 (August 6, 1985)), that some generic firms may have to reduce slightly the number of abbreviated applications they might have submitted absent user fees. But that is not realistic. If a generic firm wants to compete for a share of the propranolol or any other market, it must offer the full product line. Prescribing physicians and dispensing pharmacists are as much creatures of habit as anyone else: they are unlikely to prescribe or dispense a brand that has less than all available strengths of a therapeutic entity. Thus, the option to forego filing ANDAs for one or more strengths of a drug is really no option at all, particularly among smaller companies.

The burden of user fees would be especially heavy on contract manufacturers and distributors of "branded" generic products. These companies fill a niche that is not otherwise filled by innovator brand companies and conventional unbranded generic manufacturers and distributors. For reasons not pertinent here, many physicians and pharmacists prefer to prescribe and dispense products that are less expensive than the innovator brands while at the same time providing branded products to patients. Branded generic companies typically detail their products to physicians and provide this option. Their prices are somewhat higher than non-branded generic products, but are considerably lower than prices of innovator brands. As a consequence, these branded generics help to keep a downward pressure on drug prices.

Manufacturers and distributors of branded generics, like innovator companies, use distinctive trade dress (e.g., tablet colors) to distinguish one brand from another. If, however, a generic manufacturer makes different colored propranolol tablets for several branded distributors, six ANDAs for each color are required, even though all products are manufactured at the same facility, using the same equipment, processes and controls; both products are supported by the same bioequivalency data. What is different is minimal--stability data, dissolution data and the addition of a color to the master formula.

The result is that user fees for abbreviated applications may be disproportionate to those for full NDAs,[2/] even though the review time for ANDAs is significantly less than that for full NDAs.[3/] Theoretically, this is a problem of DGD procedure rather than of user fees, but in reality, the two are inseparable. As a result, the imposition of user fees would place the greatest burden on the generic industry.

III. The Imposition of User Fees Would Adversely Affect the Smaller Pharmaceutical Companies

The approximately 20 manufacturers in our sister association, the Generic Pharmaceutical Industry Association, account for 85% of the independently produced generic products in the United States. Of the approximately 165 members in NPA, most of these companies have sales less than $10 million per year, and some have annual sales that are considerably smaller. User charges will have a particularly adverse impact on these companies.

The medium and larger companies normally market larger quantities of product than smaller companies; thus they can recoup monies extended on user charges more quickly then can small companies. For small companies to recoup user charges quickly would require them to pass on more of the charges on a small quantity of products, thereby raising prices disproportionately. Such increases may price these companies out of the market. At best, the additional costs will mean these companies will be

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2/ When FDA proposed user charges in 1985, the agency proposed a user fee for the original application of $126,000 and a fee of $9,900 for each abbreviated application. Using propranolol as an example, a total of $59,400 in user fees would be charged for the full line of products. If a manufacturer also made a separate full line of products in a different color for a branded distributor, an additional $59,400 in user fees would be charged for each color line.

3/ In full NDAs FDA must review preclinical data (chronic toxicity studies, carcinogenicity studies, mutagenicity studies, teratogenicity studies and acute toxicity studies) and clinical data (studies in normal as well as multiple clinical investigations in controlled circumstances). None of thee data are in the ANDA counterpart, even though these data are the heart and soul of the drug approval process for new chemical entities.

providing less competition to comparable products of larger companies.

That assumes, of course, that the small companies have the wherewithal to pay user charges "up front." Some companies are so small that prepayment of user fees on a series of applications is a practical impossibility. Some of these companies will be forced to curtail making a number of products and others may be forced out of the market place entirely if caused to carry the costs of user fees while awaiting eventual approval of applications. Simultaneously, a user charge will be an additional barrier to entry to newcomers to the pharmaceutical industry. It may not be an insurmountable barrier for some, but it cannot help but be for others.

It is commonly assumed that there are great market incentives for firms to enter the generic drug market. But competitive pressures limit profits. For example, nine manufacturers had ANDAs for chlorpropamide approved on the same day. The price of the generic drug at introduction was $50.00 per 1,000 tablets; a week later, it was $25.00 per 1,000 tablets. Ultimately the price fell to $17.00 per 1,000 tablets. The public benefits, as it should, from such competition. But the profit, especially for small firms, is low -- adequate, but low. It would take along time for a small company to recoup what it paid for user charges. Companies that cannot wait that long to profit from an investment will be in jeopardy.

CONCLUSION

For the foregoing reasons, we believe that user fees for approving full, abbreviated, and certain supplemental new drug applications are an inappropriate and cost-ineffective mechanism for funding the Food and Drug Administration. User fees would pose a serious burden for the elderly and retired Americans, and would threaten the existence of many small pharmaceutical companies. We commend you for holding this hearing to air the issue of user fees.

Sincerely yours,

Jess H. Stribling

National Electrical Manufacturers Association
2101 L Street, N.W. Suite 300
Washington, D.C. 20037 (202) 457-8400
Telex 904077 NEMA WSH

Diagnostic Imaging and Therapy Systems Division

STATEMENT OF THE DIAGNOSTIC IMAGING AND THERAPY SYSTEMS DIVISION OF THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

SUBMITTED TO THE SENATE SMALL BUSINESS COMMITTEE

JUNE 13, 1989

The Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association wishes to express its opposition to the user fee proposal contained in the President's FY 1990 budget submission for the Food and Drug Administration.

As manufacturers of diagnostic imaging and x-ray equipment, it is our firm belief that these user fees constitute nothing short of a tax on innovation. As such, the proposed user fees will only stifle the research and development efforts needed to maintain American competitiveness in today's health care market.

And competitiveness is a key issue for American industry at this time. As the European Community approaches its goal of achieving a single common market by 1992, the addition of new up front expenditures to the FDA product approval process will only serve to undermine U.S. competitivness in the increasingly global marketplace for diagnostic imaging and therapy systems devices. We firmly believe that the additional up front expenditures which user fees represent would greatly impede the ability of American industry to compete, both at home and overseas.

We at NEMA believe that competitiveness is at the heart of the user fee issue -- competitiveness not only for American manufacturers abroad, but also for small manufacturers at home.

The user fee proposal, as currently drafted, will exert a particularly negative impact on small businesses. As you know, small manufacturers typically have limited capital and may experience difficulty in meeting normal day-to-day expenses.

Of the 7,627 single facility medical device manufacturers registered with the FDA, 76% are considered small business manufacturers under SBA guidelines. These 5,784 manufacturers employ 312,639 people nationwide. Twenty-eight percent (2,106) of medical device manufacturers have fewer than ten employees, forty percent have twenty or fewer employees, and fifty-four percent (4,133) have fifty or fewer employees.

To require these companies to provide "up front" money for FDA review of premarket approval applications, supplements, 510(k)'s and other FDA services mandated by law, presents an extra hurdle that is certain to force some companies out of business.

Moreover, we believe that the very nature of medical technology is incompatible with the user fee concept. Oftentimes, the pace of technological innovation is so rapid as to require the submission of separate 510(k) applications for each incremental change in product design. Under the terms of the user fee proposal, a user charge would be assessed for each separate 510(k) application. The end result of such an approach

is the imposition of a user fee at each stage of the product development process. The deleterious impact of this scheme of incremental taxation is readily apparent.

Supporters of the user fee concept contend that user fees are a necessary evil, and are the only way for the Food and Drug Administration to garner the resources necessary to efficiently fulfill its important mission of protecting the public safety and health. We take exception to this view. While we do not dispute the contention that the Food and Drug Administration lacks the resources necessary to serve as an adequate guardian of the public safety and health, we dispute the extent to which user fees would lead to increased efficiency in FDA operations. On the contrary, we believe that user fees would undermine the efficiency of the existing FDA product approval process. Since the user fee proposal, as currently structured, rests upon the costs incurred by the FDA as a result of the product approval process, the greater the resource expenditure associated with the product approval process, the greater the user fee collected by the agency. This results in a situation in which the agency has no particular incentive to control product approval costs, since these costs are recouped from industry. Clearly this is a situation which would lead to increased inefficiency in the FDA product approval process.

Finally, by increasing the costs of health care and limiting access to new and innovative technologies, it is our belief that

the user fee concept will exert a negative impact on consumers. Innovation benefits not only industry, but individuals as well. To the extent that the proposed user fees stifle innovation, they also diminish patient access to the latest health care technologies.

In conclusion, then, neither the FDA, nor industry, nor the general public will benefit from the assessment of user fees. We at NEMA urge the members of this subcommittee to disallow the user fee proposal, and to look to other sources of revenue to find the financial resources which the Food and Drug Administration needs to carry its important work into the twenty-first century.

Optikem
INTERNATIONAL INC
2122 SOUTH JASON STREET
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303/936-1137
1-800/525-1783

Senate Committee on Small Business
United States Senate
Washington, DC 20510

Dear Sirs,

The imposition of user fees for FDA review of required New Device Submissions would have a disastrous effect on small businesses in the contact lens industry. As vice-president of a small company that has submitted over 40 pre-market approval (PMAs) and supplemental premarket approval applications to FDA, I believe this would be the straw that breaks the camel's back.

We would have to change our business and develop products that are not subject to excessive regulation. This would stifle innovation in the contact lens industry since most new products are developed by small companies like ourselves. This would move the American contact lens industry even further behind foreign competition. Large foreign conglomerates (Pilkington, CIBA, Nestle) already control the industry because of government policies that punish the small American companies. We cannot compete now on the international market because FDA restricts exports of products that foreign governments do not even regulate. I also object to having to pay for bureaucratic incompetence at FDA. Our past dealings with FDA are a history of lost or misplaced applications, lengthy delays and preferential treatment of applications from large companies.

If Congress wants to really help small business it could: 1. exempt small American owned companies and let the giant foreign conglomerates pay the user fees; 2. reclassify contact lenses so we are not subject to such extreme overregulation; 3. set up an ombudsman to oversee the FDA bureaucrats so we have some recourse when we are treated unfairly.

Thank you for considering our position.

Sincerely,

William C. Hoffman

William C. Hoffman
Vice-President

Sereine